DANU-ISG-2022-01

Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap

Draft Interim Staff Guidance

May 2023

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REVIEW OF RISK-INFORMED, TECHNOLOGY-INCLUSIVE ADVANCED REACTOR APPLICATIONS—ROADMAP

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PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) staff is providing this interim staff guidance (ISG) for two reasons. First, this ISG provides guidance to facilitate the preparation of non-light water reactor (non-LWR) applications for construction permits (CPs) or operating licenses (OLs) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref.1), or combined licenses (COLs), manufacturing licenses (MLs), standard design approvals (SDAs), and design certifications (DCs) under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (Ref. 2).[1] Second, this ISG provides guidance to NRC staff on how to review such an application.

As of the date of this ISG, the NRC is developing a rule to amend 10 CFR Parts 50 and 52 (RIN 3150-AI66). The NRC staff notes this guidance may need to be updated to conform to changes to 10 CFR Parts 50 and 52, if any, adopted through that rulemaking. Further, as of the date of this ISG, the NRC is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR Part 53, "Licensing and Regulation of Advanced Nuclear Reactors," (RIN 3150-AK31). After promulgation of those regulations, the NRC staff anticipates that this guidance will be updated and incorporated into the NRC's Regulatory Guide (RG) series or a NUREG series document to address content of application considerations specific to the licensing processes in this document.

The guidance in this ISG provides (1) a general overview of the information that should be included in a non-LWR application submitted under 10 CFR Part 50 or 10 CFR Part 52; (2) a review roadmap for NRC staff with the principal purpose of ensuring consistency, quality, and uniformity of staff reviews; and (3) a well-defined base from which the staff can evaluate proposed differences in the scope of reviews (e.g., CP versus OL). Specific sections of the information described in this ISG are primarily aligned with the Licensing Modernization Project (LMP) methodology as endorsed in RG-1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology To Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," issued June 2020 (Ref. 3), as one acceptable process for applicants to use when developing portions of an application. Nonetheless, the concepts and general information in this ISG may also be used to inform the review of an application submitted using other methodologies (as applicable) such as one based on a maximum hypothetical accident or deterministic approaches. Other

[1] The NRC is issuing this ISG to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the NRC staff uses in evaluating specific issues or postulated events, and to describe information that the NRC staff needs in its review of applications for permits and licenses. The guidance in this ISG that pertains to applicants is not NRC regulations and compliance with it is not required. Methods and solutions that differ from those set forth in this ISG are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

sections of the information described in this ISG are generally applicable and independent of the methodology used to develop a non-LWR application. [2]

This ISG is being issued publicly to provide non-LWR applicants guidance for preparing their applications, to provide guidance to the staff for review of such applications, to make information about regulatory matters widely available, and to improve communication and understanding of the review process for non-LWR applications to interested members of the public. The staff anticipates that understanding of this ISG by applicants could improve the efficiency of development of their applications and navigation of the review process by providing a roadmap of items that staff will cover in it.

BACKGROUND

The NRC staff described efforts to prepare for possible licensing of non-LWR technologies in "NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness" issued December 2016 (Ref. 4). The staff then developed "NRC Non-Light Water Reactor Near Term Implementation Action Plans" (Ref. 5), and "NRC Non-Light Water Reactor Mid-Term and Long-Term Implementation Action Plans" (Ref. 6), both issued July 2017, to identify specific activities that the NRC staff would conduct in the near-term, mid-term, and long-term timeframes. Similarly, the Commission encouraged the use of a risk-informed technology-inclusive (then called "technology neutral") licensing framework for SMRs in Staff Requirements Memorandum (SRM)-COMGBJ-10-0004/COMGEA-10-0001, "Use of Risk Insights to Enhance Safety Focus of Small Modular Reactor Reviews" dated August 31, 2010 (Ref. 7), and SRM-SECY-11-0024, "Use of Risk Insights to Enhance the Safety Focus of Small Modular Reactor Reviews" dated May 11, 2011 (Ref. 8).

A key element of a new and flexible regulatory framework is a standardized process for the development of content for a non-LWR application to promote uniformity among applicants. A standardized process for the development of the content of applications for advanced reactors also ensures review consistency and predictability from NRC staff and presents a well-defined base from which to evaluate proposed changes in the scope and requirements of reviews. The development of applications for NRC licenses, certifications, and approvals is a major undertaking, in that an applicant must provide sufficient information to support the agency's safety findings. The needed information and level of detail will vary according to the design and whether an application is for a CP, SDA, DC, ML, OL, COL, or other action.

The NRC staff has had success using a standard content of application methodology for large-LWRs. The NRC's efforts to standardize the format and content of applications for LWRs are reflected in RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, LWR Edition," Revision 3, issue November 1978, (Ref. 9) and RG 1.206, "Combined License Applications for Nuclear Power Plants," issued June 2007, (Ref. 10). RG 1.206 was revised in October 2018, with the new title, "Applications for Nuclear Power Plants" (Ref. 11) and specific applicability to power reactors using LWR technology, and with the clarification that the staff also considers it to be generally applicable to other types of reactors (e.g., non-LWRs). Staff review guidance documents, such as NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,"

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[2] The guidance in this document assumes an LMP-based methodology is used to develop non-LWR application content. The NRC encourages LWR applicants seeking to use the LMP methodology to engage with the staff in pre-application discussions on the applicant's intended use of probabilistic risk assessment (PRA) tools and techniques during implementation of the LMP process for developing the content of its application.

(Ref. 12), and numerous other documents on specific technical areas address the suggested scope and level of detail for applications. While it is not the purpose of this document to re-create a NUREG-0800 type broad spectrum of review guidance for non-LWRs, the staff intends to leverage the previous experience and insights gained from having the benefit of standard application content principles in this document.

To standardize the development of content in a non-LWR application, the staff has focused on two activities: the Advanced Reactor Content of Application Project (ARCAP), and the Technology-Inclusive Content of Application Project (TICAP).

ARCAP is an NRC-led activity that is intended to result in guidance for a complete non-LWR application for review under 10 CFR Part 50 or 10 CFR Part 52, and that when updated would be applicable to the ongoing 10 CFR Part 53 rulemaking effort. As a result, ARCAP is broader than and encompasses several industry-led and NRC-led guidance document development activities aimed at facilitating a consistent approach to the development of application documents. A complete non-LWR application is required to include a safety analysis report (SAR), a Quality Assurance (QA) plan, a Fire Protection program, Emergency Preparedness and Physical Security plans, etc. The information described in this ISG summarizes the results of the NRC-led ARCAP efforts.

TICAP is an industry-led activity that is focused on providing guidance on the appropriate scope and depth of information related to the specific portions of the SAR that describe the fundamental safety functions of the design and details the safety information pertinent to a facility using the LMP approach. The specific portions of the SAR addressed by TICAP are described below in more detail. Because of the limited scope of the TICAP guidance, it is encompassed by and supplemented by the ARCAP guidance, which will cover the areas of the SAR that are outside the scope of the LMP process and TICAP, such as site information and information relating to the use of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel Code (Code), Section III, Division 5, for construction of reactor SSCs for high temperature applications.

Figure 1 below illustrates the relationship between guidance produced under ARCAP and TICAP and other guidance for the review of non-LWR applications.

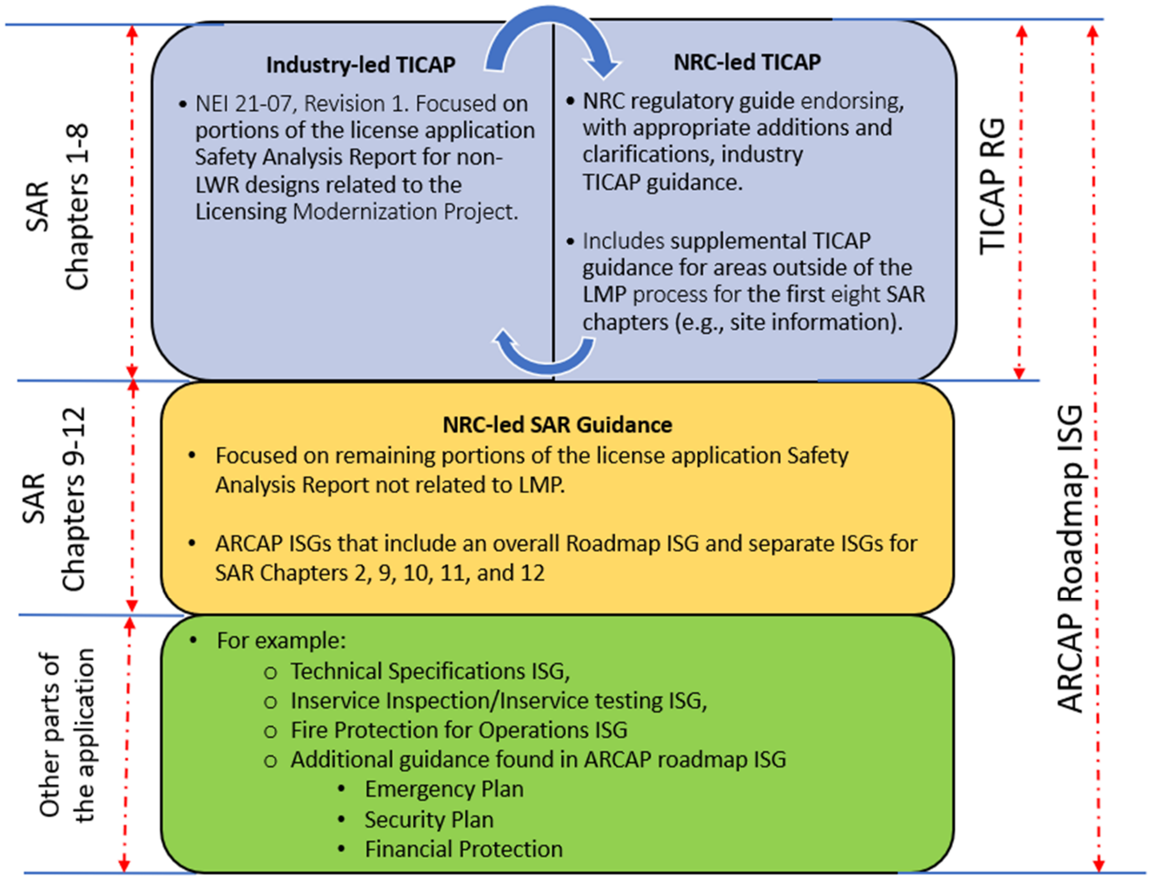

Figure 1: Relationship between ARCAP, TICAP, and the content of an application

The LMP process is described in Nuclear Energy Institute (NEI) document NEI 18–04, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," Revision 1, issued August 2019 (Ref. 13), which is endorsed by the NRC in RG 1.233. The LMP methodology outlines an approach for use by a power reactor applicant to identify and select licensing basis events (LBEs) applicable to its facility and the site under consideration, classify structures, systems, and components (SSCs), determine special treatments and programmatic controls, and assess the adequacy of a design in terms of providing layers of defense-n-depth (DID). In addition, the LMP methodology and RG 1.233 describe a general approach for identifying an appropriate scope and depth of information that applicants for licenses, certifications, and approvals should provide. The content formulation should optimize the type and level of detail of information provided, based on the complexity of the design's safety analysis and the nexus between elements of the design and public health and safety.

In its "Policy Statement on the Regulation of Advanced Reactors," the Commission "encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs" (73 FR 60612, 60616; October 14, 2008) (Ref. 14). These pre-application interactions with prospective applicants may be initiated once a prospective applicant has indicated sufficient commercial interest, organizational capacity, design maturity, and plans for an application submittal to support commencement of meaningful regulatory discussions with NRC staff. Appendix A to this document provides preapplication engagement guidance.

In addition to reflecting a well-defined standard content of application methodology, the scope of information in the application and its level of detail should be commensurate with the type of application submitted (CP, early site permit (ESP), DC, COL, etc.), the reactor design and technology described in the application, and the safety and risk significance of the reactor and facility SSCs. Determining the appropriate scope and level of detail of technical and programmatic information described above is a key part of developing any non-LWR application using a risk-informed and performance-based approach. That scope of information and level of detail for the design should be supplemented with the safety justifications prepared by the applicant and consideration of all regulatory requirements the NRC and other agencies have established. To inform the review of the licensing basis information of a non-LWR application independent of the specific design or methodology used, the staff should use Appendix B of this document, which describes the regulations that are generally applicable to non-LWR applications for CPs and OLs under 10 CFR Part 50 and DCs, COLs, and SDAs under 10 CFR Part 52.

For applicants using the 10 CFR Part 50 process, application requirements include those in 10 CFR 50.34, “Contents of applications; technical information.” For applicants using the 10 CFR Part 52 process, application requirements for ESPs include those in 10 CFR 52.17 “Contents of applications; technical information,” and for COLs the application requirements include those in 10 CFR 52.79 “Contents of applications; technical information in final safety analysis report.” Additionally, the 10 CFR Part 52 process application requirements for standard design certifications, SDAs, and MLs include those in Sections 10 CFR 52.47, 52.137, and 52.157, respectively.[3]

The guidance resulting from TICAP and ARCAP covers the following elements of a non-LWR application:[4]

- SAR[5]
- technical specifications
- technical requirements manual
- quality assurance (QA) plan
- fire protection program (design)
- probabilistic risk assessment
- emergency preparedness

[3] The NRC staff plans to update the guidance in this document depending on the results of a rulemaking in progress to prepare new regulations (currently designated as “10 CFR Part 53”) to adopt risk-informed, performance-based, technology-inclusive requirements for licensing new nuclear reactors. The goal of the 10 CFR Part 53 rulemaking effort is to develop an additional optional regulatory framework for the licensing of nuclear reactors.

[4] The need for submittal of certain information in this list will depend on the regulatory path of an application. Additional items to support an application required under the content of applications, general information regulations (e.g., § 50.33) is not covered by TICAP/ARCAP guidance.

[5] Requirements for the contents of a final safety analysis report (FSAR) are provided in 10 CFR 50.34(b) and include items such as technical specifications and emergency plans, as well as other technical and programmatic contents listed there. It should be noted that items such as technical specifications and emergency plans may be incorporated by reference in the FSAR but are controlled by change processes other than 10 CFR 50.59 for OLs. For example, changes to the technical specifications, which are part of the license, require a license amendment, and emergency plan changes are controlled by 10 CFR 50.54(q).

- security plans
- cyber security plan
- special nuclear material (SNM) control and accountability
- fire protection program (operational)
- radiation protection program
- offsite dose calculation manual
- inservice inspection (ISI) and inservice testing (IST)
- environmental report and site redress plan
- financial qualification and insurance and liability
- fitness for duty
- facility safety program (reserved)
- inspections, tests, analysis and acceptance criteria (ITAAC)
- aircraft impact assessment
- performance demonstration requirements
- Nuclear Waste Policy Act
- operational programs

This ISG provides information and references for the application components identified above. The guidance in this ISG leverages:

- industry-led guidance (as endorsed),
- NRC-developed guidance for non-LWRs,
- existing guidance the NRC staff has found generally applicable to advanced reactors, and
- insights from rulemakings and guidance currently under development

Subsequent revisions to this ISG will incorporate additional guidance as it is identified and developed.

RATIONALE

The current guidance for contents of applications in RG 1.206 and RG 1.70 is primarily directed to LWRs and may not identify the information to be included in an application based on a technology-inclusive, risk-informed, and performance-based approach to reactor design and operation. The development of a new standard content of application is warranted to assist applicants in preparing non-LWR applications. Similarly, the current staff review guidance in NUREG-0800 directly applies only to LWRs. While some portions of the SRP can be applied to non-LWRs, NUREG-0800 may not provide a complete set of guidance for reviewing non-LWR applications, particularly those that employ technology-inclusive, risk-informed, and performance-based approaches. Accordingly, additional guidance is warranted to support staff readiness to perform consistent and predictable licensing reviews of non-LWR technologies. This ISG serves as the non-LWR application roadmap for this effort. This ISG provides both applicant content of application and NRC staff review guidance.

APPLICABILITY

This ISG applies to the preparation and review of non-LWR[6] applications for permits and licenses that submit risk-informed, performance-based applications for CPs or OLs under

[6] An applicant desiring to use this ISG for a light water reactor application should contact the NRC staff to hold preapplication discussions on its proposed approach.

10 CFR Part 50 or for COLs, SDAs, DCs, or MLs under 10 CFR Part 52. This ISG is also applicable to the NRC staff reviewers of these applications.

PAPERWORK REDUCTION ACT

This ISG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 50 and 52 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0011 and 3150-0151. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0011 and 3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

GUIDANCE

Safety Analysis Report

Under § 50.34(a), an applicant for a CP shall include a preliminary SAR (PSAR) as part of its application. Under §§ 50.34(b) and 52.79, an applicant for an OL or a COL shall include a final SAR (FSAR) in its application. Similarly, under §§ 52.47(a), 52.137(a), and 52.157, an application for a DC, SDA, or an ML, respectively, must include a FSAR. The SAR must include information that describes the facility, presents the design bases and the limits on facility operation, and present a safety analysis of the SSCs and of the facility as a whole. Because a SAR for an SDA, DC, or ML can be limited in scope in certain ways, the SAR must include a safety analysis of the SSCs within the scope of the SDA, DC, or ML application. In general, the PSAR for a CP application or a FSAR for other applications must be sufficiently detailed to permit the staff to determine whether the application satisfies the standards for issuing the requested license, certification, or approval, set in the regulations for the requested action. For CP, OL, COL, and ML applications, those standards include whether the plant can be built and operated without undue risk to the health and safety of the public. Prior to submission of an PSAR or FSAR, an applicant should have designed and analyzed the plant in sufficient detail to conclude that it can be built and operated safely. The PSAR or FSAR is the principal document in which the applicant states the information the staff needs to understand the basis upon which the staff can make its findings. Additional discussion regarding acceptable content of information to be included in a PSAR can be found in Appendix C, "Construction Permit Guidance," of this document.

In a series of public interactions with stakeholders, the NRC staff discussed a 12-chapter structure for developing the SAR as one acceptable approach for an advanced reactor application. The 12-chapter approach is largely aligned with the LMP methodology, which revolves around describing the safety analysis for the facility. Pre-application engagement with applicants is encouraged to optimize resources and review schedule. The 12-chapter structure for the SAR follows:

- Chapter 1 – General Plant Information, Site Description, and Overview of the Safety Analysis
- Chapter 2 – Methodologies, Analyses, and Site Evaluations
- Chapter 3 – Licensing Basis Events
- Chapter 4 – Integrated Evaluations
- Chapter 5 – Safety Functions, Design Criteria, and SSC Categorization
- Chapter 6 – Safety-Related SSC Criteria and Capabilities
- Chapter 7 – Non-Safety-Related with Special Treatment (NSRST) SSC Criteria and Capabilities
- Chapter 8 – Plant Programs
- Chapter 9 – Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste
- Chapter 10 – Control of Occupational Dose
- Chapter 11 – Organization and Human-Systems Considerations
- Chapter 12 – Post Construction Inspection, Testing, and Analysis Program.

The format and content above are one approach to develop and organize the contents of the SAR, but applicants have the discretion to identify alternate approaches to accommodate a variety of site conditions and plant designs. If an applicant chooses a different organizational structure for its FSAR, it should identify this to the staff during preapplication discussions.

Staff Review Guidance

Where a particular applicant uses an alternate to this SAR approach, staff reviewers should focus on any deviations from and exceptions to the review guidance regarding requested information and the organization of the information. Reviewers must ensure that the applicant submits the information necessary for the staff to determine whether the staff has a basis for making the findings specified for each particular type of application. For an application for a CP, OL, COL, or ML, the required findings include whether there is reasonable assurance that the plant can be built and operated without undue risk to the health and safety of the public.

SAR Chapters 1-8

Overview

SAR chapters 1-8 are largely focused on describing the fundamental safety functions of the design and the safety analysis for each application consistent with the LMP approach. The industry-led TICAP effort resulting in guidance for these chapters is documented in NEI 21-07, “Technology Inclusive Guidance for Non-Light Water Reactors Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology,” Revision 1, issued February 2022 (Ref. 15). NEI 21-07, Revision 1, describes the scope and level of detail in specific portions of the first eight chapters of the SAR that are associated with the LMP-based safety analysis.

The NRC staff reviewed NEI 21-07, Revision 1, and endorsed the guidance as one acceptable approach to develop portions of the first eight chapters of the SAR in Draft Regulatory Guide (DG) 1404, “Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors,” (Ref. 16). DG 1404 includes additional clarifications, additions, points of emphasis, and further details relevant to the specific sections discussed in NEI 21-07. In addition, DG 1404 describes additional information outside the scope of LMP and NEI 21-07 that NRC staff has determined is also relevant and should be included in the first eight chapters of the SAR or otherwise provided in the application.

Guidance Documents that are Referenced in DG-1404

Additional guidance documents referred to in this DG may provide useful information to applicants, the NRC staff, or both. *(Note that DG-1404 provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance documents provided below the applicable NRC endorsement document must be considered for any exceptions, clarifications, or additions associated with the use of these guidance documents. In addition, Appendix D of this document, “Draft Advanced Reactor Content of Application Project (ARCAP) Guidance Documents Under Development as of November 2022,” provides a list of references that are under development in this area.)*

- NRC, RG 1.70, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)”
- NRC, RG 1.181, “Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71I”
- NRC, RG 1.206, “Applications for Nuclear Power Plants”
- NRC, RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors”
- RG 1.233, “Guidance for a Technology Inclusive, Risk Informed, and Performance Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors”
- NUREG-0933, Resolution of Generic Safety Issues (Formerly entitled "A Prioritization of Generic Safety Issues") (NUREG-0933, Main Report with Supplements 1–35)
- RG 1.217, Revision 0, “Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts”

- NEI 07-13, Revision 8P, “Methodology for Performing Aircraft Impact Assessments for New Plant Designs”
- RG 1.226, Revision 0, “Flexible Mitigation Strategies for Beyond-Design-Basis Events”
- NEI 12-06, Revision 4, “Diverse and Flexible Coping Strategies (FLEX) Implementation Guide”
- RG 1.227, Revision 0, “Wide-Range Spent Fuel Pool Level Instrumentation”
- NEI 12-02, Revision 1, “Industry Guidance for Compliance with NRC Order EA-12-051, ‘To Modify Licenses with Regard to Reliable Spent Fuel Pool Instrumentation’”
- NEI 06-12, Revision 2, “B.5.b Phase 2 & 3 Submittal Guideline”
- NUREG-0800, Section 19.4, “Strategies and Guidance to Address Loss-of-Large Areas of the Plant Due to Explosions and Fires”
- RG 1.201, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance”
- RG 1.206, Revision 0, “Combined License Applications for Nuclear Power Plants (LWR Edition)”
- RG 1.247 (for Trial Use), “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk Informed Activities”
- RG 1.87. Revision 2, “Acceptability of ASME Section III, Division 5, ‘High Temperature Reactors’”
- NUREG-2246, “Fuel Qualification for Advanced Reactors”
- “Design Review Guide (DRG): Instrumentation and Controls for Non-Light-Water Reactor (Non-LWR) Reviews”
- ASME Boiler and Pressure Vessel Code, Section III, Division 5, “High Temperature Reactors”
- ASME/American Nuclear Society RA-S-1.4-2021, “Probabilistic Risk Assessment Standard for Advanced Non-Light-Water Reactor Nuclear Power Plants”
- NEI 20-09, “Performance of PRA Peer Reviews Using the ASME/ANS Advanced Non-LWR PRA Standard”
- Electric Power Research Institute (EPRI) EPRI-AR-1(NP)-A, “Uranium Oxycarbide (UCO) Tristructural Isotropic (TRISO)-Coated Particle Fuel Performance"

Site Evaluation Guidance

The TICAP guidance (i.e., NEI 21-07, and DG 1404) for SAR Chapter 2 provides guidance for the methodologies and analyses portion of the SAR, but it is limited in the guidance that it provides regarding applicant site evaluations. Although an applicant can evaluate some site criteria using the LMP process on which the TICAP guidance is based, the LMP process does not provide guidance to adequately address the complete set of site evaluations necessary to satisfy reactor siting requirements and to support a regulatory decision. The guidance for developing application content for site evaluations is described in DANU-ISG-2022-02, "Chapter 2, 'Site Information'" (Ref. 17).

Staff Review Guidance

The staff review guidance for site evaluations can also be found in DANU-ISG-2022-02, "Chapter 2, 'Site Information.'"

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-02 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references.)*

- RG 1.23, "Meteorological Monitoring Program for Nuclear Power Plants"
- RG 1.27, "Ultimate Heat Sink for Nuclear Power Plants"
- RG 1.59, "Design Basis Floods for Nuclear Power Plants"
- RG 1.76, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants"
- RG 1.91, "Evaluation of Explosions Postulated to Occur at Nearby Facilities and on Transportation Routes Near Nuclear Power Plants"
- NUREG-0800, Section 3.5.1.6, "Aircraft Hazards"
- RG 1.102, "Flood Protection for Nuclear Power Plants"
- RG 1.111, "Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water Cooled Reactors"
- RG 1.132, "Site Investigations for Foundations of Nuclear Power Plants"
- RG 1.138, "Laboratory Investigations of Soils and Rocks for Engineering Analysis and Design of Nuclear Power Plants"
- RG 1.145, "Atmospheric Dispersion Models for Potential Accident Consequence Assessment at Nuclear Power Plants"

- RG 1.194, “Atmospheric Relative Concentrations for Control Room Radiological Habitability Assessments at Nuclear Power Plants”
- RG 1.198, “Procedures and Criteria for Assessing Seismic Soil Liquefaction at Nuclear Power Plant Sites”
- RG 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion”
- RG 1.221, “Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants”
- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors”
- RG 1.247 (for Trial Use), “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities”
- RG 1.70, “Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants”
- RG 4.2, “Preparation of Environment Reports for Nuclear Power Stations”
- RG 4.26, “Volcanic Hazards Assessment for Proposed Nuclear Power Reactor Sites”
- RG 4.7, “General Site Suitability Criteria for Nuclear Power Stations”
- Staff Requirements Memorandum, “Staff Requirements – SECY-20-0045 – Population-Related Siting Considerations for Advanced Reactors,” dated July 13, 2022
- NUREG/CR-2858, “PAVAN: An Atmospheric Dispersion Program for Evaluating Design Basis Accidental Releases of Radioactive Materials from Nuclear Power Plants,” November 1982
- NUREG/CR-2919, “XOQDOQ: Computer Program for the Meteorological Evaluation of Routine Effluent Releases at Nuclear Power Stations,” September 1982
- NUREG-2115, “Central and Eastern US Seismic Source Characterizations for Nuclear Facilities”
- NUREG-2213, “Updated Implementation Guidelines for SSHAC Hazard Studies,” October 2018

Design of Structures, Components, Equipment, and Systems

The TICAP guidance (i.e., NEI 21-07 and DG 1404) for the design of structures, components, and equipment and systems would generally place this information in SAR Chapters 5 and 6 following the LMP process. The SAR (Chapters 5 and 6) should describe, in part, the analytical methods used and a summary of results regarding:

- the translation of design basis hazard levels to loads on SSCs, evaluation of those loads,
- identification of, and protection from internally generated missiles including the design of structures, shields and barriers to withstand the effects of missile impact,
- the evaluation of piping failures of fluid systems and dynamic effects of piping ruptures

Associated calculations should be made available for staff audit. NEI 21-07, notes that design basis hazard levels (DBHLs) can be selected probabilistically (in accordance with the LMP process) or deterministically. If the DBHLs are chosen probabilistically, the details behind the DBHLs reside in the PRA documentation. If applicants propose methods to identify DBHLs that the NRC staff has not previously reviewed and approved, the staff will review the proposed methodologies and any needed exemptions on a case-by-case basis. If the DBHLs are chosen deterministically, the basis for the selection of DBHLs should be described in the SAR. The applicant should also address applicable requirements that are outside the scope of the LMP process, such as 10 CFR Part 50, Appendix S, as it relates to meeting the capabilities and performance of the instrumentation system to adequately measure the effects of earthquakes. 10 CFR Part 50, Appendix S, Paragraph IV(a)(4) requires that suitable instrumentation be provided to promptly evaluate the seismic response of nuclear power plant features important to safety after an earthquake.

Staff Review Guidance

Applicable staff review guidance is found is NUREG-0800 Chapter 3, “Design of Structures, Components, Equipment, and Systems.” Certain sections of NUREG-0800 Chapter 3 (e.g., those associated with a containment) may not be applicable based on the reactor design and the outcome of the LMP process. NUREG-0800 provides guidance on the translation of DBHLs to loads on SSCs, the evaluation of those loads, and related design analyses. If the DBHLs are chosen deterministically, guidance associated with external hazards can be found in DANU-ISG-2022-02, discussed above.

Guidance regarding the identification of, and protection from internally generated missiles can be found in the following NUREG-0800 sections:

- Section 3.5.1.1, “Internally Generated Missiles (Outside Containment),” (Ref. 18)
- Section 3.5.1.2, “Internally Generated Missiles (Inside Containment),” (Ref. 19)
- Section 3.5.1.3, “Turbine Missiles,” (Ref. 20)

Guidance regarding procedures utilized in the design of structures, shields, and barriers to withstand the effects of missile impact can be found in NUREG-0800 Section 3.5.3, “Barrier Design Procedures,” (Ref. 21). As applicable, guidance regarding the evaluation of piping failures of fluid systems and dynamic effects of piping ruptures, can be found in the following NUREG-0800 Sections:

- Section 3.6.1, “Plant Design for Protection Against Postulated Piping Failures in Fluid Systems Outside Containment,” (Ref. 22)

- Section 3.6.2, “Determination of Rupture Locations and Dynamic Effects Associated with the Postulated Rupture of Piping,” (Ref. 23)

- Section 3.6.3, “Leak-Before-Brea Evaluation Procedures,” (Ref. 24)

SAR content regarding the topics above should describe the analytical methods used and a summary of the results. Associated calculations should be available for staff audit.

For inservice inspection and inservice testing, the staff should refer to DANU-ISG-2022-07, “Risk-informed ISI/IST Programs,” which is described later in this document. Aircraft hazards associated with nearby airports, federal airways, holding and approach patterns, military airports, training routes, and training areas should be assessed in accordance with DANU-ISG-2022-02 Section 2.3. Seismic instrumentation requirements should be evaluated in accordance with NUREG-0800 Section 3.7.4, “Seismic Instrumentation” (Ref. 25).

Construction Permit Guidance

NEI’s TICAP guidance document, NEI 21-07, Revision 1, includes guidance for developing portions of a CP application under 10 CFR Part 50. However, for non-LWR applicants pursuing a CP under Part 50, additional information unrelated to an LMP-based safety analysis should be provided. Specifically, 10 CFR 50.34(a) identifies the minimum technical information necessary in a CP application. Under 10 CFR 50.35(a), when the applicant has not supplied all of the technical information required to support the issuance of a CP that approves all proposed design features, the Commission may issue a CP provided that the Commission makes the findings identified in that section. The CP applicant may also provide the technical information necessary to support approval of specific design features or specifications in accordance with 10 CFR 50.35(b). DG 1404 provides additional guidance on the information necessary to supplement the first eight Chapters of a CP SAR. As previously stated, SAR chapters 1-8 are largely focused on describing the fundamental safety functions of the design and the safety analysis for an application consistent with the LMP approach. Appendix C provides additional information that is applicable to SAR Chapter 1-8 as well as guidance for other portions of the application that are outside the scope of these SAR Chapters.

Developing Proposed Principal Design Criteria (PDC) for Those Aspects of the Facility Design not Informed by the LMP Process (e.g., Normal Operations)

Pursuant to 10 CFR 50.34 and 10 CFR 52.47, 52.79, 52.137, and 52.157, an applicant must provide PDC in its license application as a means to meet the Atomic Energy Act (AEA), Section 182 requirement that applications include:

> …the specific characteristics of the facility, and such other information as the Commission may, by rule, or regulation, deem necessary in order to enable it to find that the utilization or production of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public.

In addition to the requirement to propose PDC in an application, the NRC has also determined that the requirement to propose PDC includes a requirement to address the full scope of PDCs described in the regulations which includes…”design, fabrication, construction, testing and performance requirements for structures, system, and components important to safety.” Further, the NRC has determined that for applicants using the LMP process described in

NEI 18-04, Revision 1, and endorsed in RG 1.233, SSCs classified as safety related (SR) and NSRST are important to safety.

NEI 21-07, Revision 1, includes guidance for developing proposed PDCs for those aspects of the facility design that focus on those design functions and features that are SR and those that are NSRST. NEI 21-07, Rev. 1, provides an approach for developing a two-tiered structure for PDCs that include those developed for required functional design criteria (RFDCs) and complementary design criteria (CDC), as defined in NEI 21-07, Rev. 1, which also correlate with design functions classified as SR and NSRST, respectively. The NRC endorses this approach to developing LMP-based proposed PDCs in its TICAP guidance in DG-1404. The NRC also considers this approach to be appropriate for developing proposed PDCs for those design functions and features of the facility that are SR and NSRST and not informed by the LMP process (e.g., normal operations). As indicated in Appendix A to Part 50, the general design criteria (GDC) are intended to provide guidance in establishing PDCs for reactors that are not water cooled. Applicants may use the advanced reactor design criteria (ARDC) developed in RG 1.232, "Developing Principal Design Criteria for Non-Light Water Reactors (Ref. 26), to inform the development of their proposed PDCs, as these were derived from the GDCs

Although not required, it may be efficient for an applicant to include all proposed PDCs developed for its facility application in Chapter 5 of its SAR regardless of whether they were developed using the LMP process or not. The chapters of the SAR that discuss the subject matter related to specific proposed PDCs may either reference or reproduce those proposed PDCs described in the specific portion of an application that are outside the scope of the LMP process. For example, PDCs developed for radiation protection, as discussed in the guidance found in DANU-ISG-2022-03, "Chapter 9, 'Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste,'" (Ref. 27), could be included in SAR Chapter 5 with a reference to SAR Chapter 9 for a more complete description and basis for the PDC.

Applicants may adopt alternative approaches to proposing PDC for those aspects of the facility design not informed by the LMP process. If these approaches are based on similar risk-informed, performance-based licensing methodologies, the applicant should provide suitable justification for their use and request any necessary exemptions. Exemptions are necessary if applicants do not propose full scope PDCs, as discussed above — that is, if the PDC do not cover all necessary design, fabrication, construction, testing, and performance requirements for all SSCs important to safety. For example, the justification may be that, to address specific elements of PDC scope not included, the applicant has complied with other regulatory requirements that compel the applicant to provide the relevant information in other portions of the application.

Chapter 9–- Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste

Overview – Application Guidance

Nuclear power plants generate liquid, gaseous, and solid waste during normal operations and must have processes to contain, store, and release these wastes under NRC regulations. In general, the information in this chapter should provide details associated with the waste management systems that ensure the requirements of 10 CFR Parts 20, "Standards for protection against radiation" (Ref. 28), 50, 52, and 61, "Licensing requirements for land disposal of radioactive waste” (Ref. 29), are met, or propose alternative requirements and any necessary exemptions consistent with the technology of the proposed reactor design.

Each waste management system included in the design should be described in Chapter 9 of the SAR. That description should include discussion of the specific functions performed by the system, the sources of normal radioactive liquid and gaseous waste, including the general quantities and composition of liquid and gaseous radioactive waste anticipated to be contained in the system, any performance monitoring of the system, and a risk-informed approach to demonstrate compliance with the applicable regulations.

The guidance for developing application content for Chapter 9 is described in DANU-ISG-2022-03, “Chapter 9, ‘Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste.’”

Staff Review Guidance

The staff review guidance for SAR Chapter 9 can also be found in DANU-ISG-2022-03.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-03 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance document provided below the applicable NRC approval document must be considered for any exceptions, clarifications, or additions associated with the use of this guidance document.)*

- RG 1.206, “Applications for Nuclear Power Plants”
- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors”
- RG 1.143, “Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants”
- RG 4.21, “Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning”
- NUREG/BR-0303, “Guidance for Performance-Based Regulation”
- NEI 07-10A, Revision 0, “Generic FSAR Template Guidance for Process Control Program (PCP)”

Chapter 10 - Control of Occupational Dose

Overview – Application Guidance

The information in this chapter should describe the facility and equipment design, radiation sources, and operational programs that are credited to ensure that the occupational radiation protection standards set forth in 10 CFR Part 20 are met. The information should also include any commitments made by the applicant to develop the management, policy, and organizational structure necessary to ensure occupational radiation exposures are as low as is reasonably achievable (ALARA).

The guidance for developing application content for Chapter 10 is described in DANU-ISG-2022-04, "Chapter 10, 'Control of Occupational Dose'" (Ref. 30).

Staff Review Guidance

The staff review guidance for SAR Chapter 10 can also be found in DANU-ISG-2022-04.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-04 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance document provided below the applicable NRC approval document must be considered for any exceptions, clarifications, or additions associated with the use of this guidance document.)*

- RG 1.206, "Applications for Nuclear Power Plants"
- RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light Water Reactors"
- NEI 07-08A, "Generic FSAR Template Guidance for Ensuring that Occupational Radiation Exposures Are as Low as Is Reasonably Achievable (ALARA)"

<u>Chapter 11 – Organization and Human-Systems Considerations</u>

Overview – Application Guidance

The information in this chapter should describe the organizational structure and key management positions in the design, construction and operating organizations that are responsible for facility design, design review, design approval, construction management, testing, and operation of the plant. In addition, the information in this chapter should describe the most important human factors engineering (HFE) issues for a particular applicant and demonstrate how the applicant's HFE program incorporates HFE practices and guidelines that satisfy the current requirements. The HFE review covers the HFE design process, the HFE final design, its implementation, and ongoing performance monitoring, including the ongoing confirmation of human reliability and capability targets (where applicable).

The guidance for developing application content for Chapter 11 is described in DANU-ISG-2022-05, "Chapter 11, 'Organization and Human-Systems Considerations'" (Ref. 31).

Staff Review Guidance

The staff review guidance for SAR Chapter 11 can also be found in DANU-ISG-2022-05.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-05 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance documents provided below the applicable NRC endorsement or approval document must be considered for any exceptions, clarifications, or additions associated with the use of these guidance documents.)*

- NUREG-0800, Chapter 18, “Human Factors Engineering”
- NUREG-0800, Chapter 1, “Introduction and Interfaces”
- NUREG-0711, “Human Factors Engineering Program Review Model”
- NUREG-1791, “Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)”
- RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants”
- NUREG-1021, “Operator Licensing Examination Standards for Power Reactors”
- RG 1.149, “Nuclear Power Plant Simulation Facilities for Use in Operator Training and License Examinations”
- Nuclear Energy Institute (NEI) 06-13A, “Template for an Industry Training Program Description”
- RG 1.33, “Quality Assurance Program Requirements (Operation)”
- American National Standards Institute/American Nuclear Society, ANSI/ANS-3.2-2012, “Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants”
- American National Standards Institute/American Nuclear Society, ANSI/ANS-3.1-2014, “Selection, Qualification, and Training of Personnel for Nuclear Power Plants”
- Institute of Electrical and Electronics Engineers Standard 603–1991, “IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations”
- “Memorandum of Agreement Between the Institute of Nuclear Power Operations and the U.S. Nuclear Regulatory Commission”
- “Commission Policy Statement on Engineering Expertise on Shift,” *Federal Register*, Vol. 50, October 28, 1985, pp. 43621–43623
- NUREG-0737, “Clarification of TMI Action Plan Requirements,” November 1980

- RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light Water Reactors”

Chapter 12 – Post Construction Inspection, Testing, and Analysis Program

Overview – Application Guidance

The information in this chapter should describe the post-construction inspection, testing, and analysis program (PITAP) in the application. The PITAP ISG consists of guidance related to post-construction inspection, preoperational testing (i.e., tests conducted following construction and construction-related testing, but prior to initial fuel load), analysis, verification, and initial startup testing (i.e., tests conducted during and after initial fuel load, up to and including initial power ascension). The primary objective of the PITAP is to demonstrate, to the extent possible, that the SR and safety-significant (SS) SSCs operate in accordance with the design and as credited in the safety analysis.

The guidance for developing application content is described in DANU-ISG-2022-06, “Chapter 12- ‘Post Construction Inspection, Testing, and Analysis Program’” (Ref. 32).

Staff Review Guidance

The staff review guidance for SAR Chapter 12 can also be found in DANU-ISG-2022-06.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-06 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance document provided below the applicable NRC endorsement document must be considered for any exceptions, clarifications, or additions associated with the use of this guidance document.)*

- NUREG-0800, Section 14.2, “Initial Plant Test Program - Design Certification and New License Applicants”
- NUREG-0800, Section 14.3, “Inspections, Tests, Analyses, and Acceptance Criteria”
- RG 1.68, “Initial Test Programs for Water-Cooled Nuclear Power Plants”
- ASME Boiler and Pressure Vessel Code, Section III, “Rules for Construction of Nuclear Facility Components”

Technical Specifications

Overview – Application Guidance

In general, Technical Specifications (TS) are part of an NRC license authorizing the operation of a nuclear production or utilization facility. A technical specification establishes requirements for items such as safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features, and administrative controls.

Section 182a. of the Atomic Energy Act of 1954, as amended, requires applicants for nuclear power plant operating licenses to state the following:

> [S]uch technical specifications, including information of the amount, kind, and source of special nuclear material required, the place of the use, the specific characteristics of the facility, and such other information as the Commission may, by rule or regulation, deem necessary in order to enable it to find that the utilization...of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. Such technical specifications shall be a part of any license issued.

In 10 CFR 50.36, "Technical Specifications," the Commission established its regulatory requirements related to the content of TS. For a non-LWR application, applicants may use a risk-informed design process, which may result in the applicant's developing some proposed TS under 10 CFR 50.36(c)(2)(ii)(D). (This will not exclude TS under the other provisions of section 50.36(c)(2)(ii).)

The guidance for developing application content is described in DANU-ISG-2022-08, "Risk-Informed Technical Specifications'" (Ref. 33).

Staff Review Guidance

The staff review guidance for TSs can also be found in DANU-ISG-2022-08.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-08 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance document provided below the applicable NRC approval must be considered for any exceptions, clarifications, or additions associated with the use of this guidance document.)*

- RG 1.33, "Quality Assurance Program Requirements (Operation)"
- RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis"
- RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications"
- NUREG-0800, Chapter 16, "Technical Specifications."
- "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors," 58 FR 44071, July 22, 1993
- NUREG-1431, Volume 1, "Standard Technical Specifications—Westinghouse Plants: Specifications"

- “Final Safety Evaluation for Nuclear Energy Institute (NEI) Topical Report (TR) 04-10, Revision 1, “Risk-Informed Technical Specification Initiative 5B, “Risk -Informed Method for Control of Surveillance Frequencies,” September 19, 2007

- NEI 04-10, “Risk-Informed Method for Control of Surveillance Frequencies”

Technical Requirements Manual

Overview – Application Guidance

Technical Requirements Manuals (TRMs) are not required as separate documents under 10 CFR Parts 50 and 52 but have been used to address (i) requirements that have previously been addressed in TSs, but later removed, and for documenting (ii) controls associated with the Regulatory Treatment of Nonsafety Systems (RTNSS) for light water reactors (LWRs). (The information in a TRM is typically incorporated by reference in a facility FSAR or included as a general reference in the FSAR.)

TRMs were developed as a result of the Improved Technical Specifications (ITS) and Standard Technical Specifications (STS) efforts). As the ITS and STS were implemented, licensees removed items from their TS that did not meet the updated criteria in the 10 CFR 50.36 requirements promulgated in a final rule published in 1995 (Technical Specifications, 60 FR 36953; July 19, 1995) and relocated those items to licensee-controlled documents that were typically incorporated by reference into final safety analysis reports (FSARs) and subject to the 10 CFR 50.59 change process. Discussions contained in the statements of consideration for the 1995 final technical specification rule update provide the following background:

> Technical specifications cannot be changed by licensees without prior NRC approval. However, since 1969, there has been a trend toward including in technical specifications not only those requirements derived from the analyses and evaluation in the safety analysis report but also essentially all other Commission requirements governing the operation of nuclear power reactors. This extensive use of technical specifications was due in part to a lack of well-defined criteria (in either the body of the rule or in some other regulatory document) for what should be included in technical specifications. Since 1969, this use has contributed to the volume of technical specifications and to the several-fold increase in the number of license amendment applications to effect changes to the technical specifications. It has diverted both NRC staff and licensee attention from the more important requirements in these documents to the extent that it has resulted in an adverse but unquantifiable impact on safety.

Since promulgation of the updated requirements for technical specifications, the NRC has approved STS for various LWR designs.

Guidance provided in RG 1.206 for new LWRs indicates that the format and content of the TS and bases for a COL application not referencing a certified design should be based on the most recent version of the STS appropriate to the NSSS design. Applicants for advanced reactors should refer to DANU-ISG-2022-08, “Risk-Informed Technical Specifications” for guidance in developing appropriate TS for their designs.

The TRM may provide a convenient vehicle to document and maintain special treatment requirements for SSCs classified as NSRST under the LMP methodology. The LMP methodology includes the identification and implementation of special treatment of those SSCs found to be risk significant due to their roles in preventing or mitigating specific event sequences or their contributions to one of the cumulative risk metrics. In addition, as RG 1.233 describes, the LMP methodology calls for the reactor designer to put in place an integrated decision process (IDP) to evaluate and document the defense in depth of the design, which may result in the development of information that can be controlled through the TRM. For example, as noted in RG 1.233, a plant feature may be one of several means needed to ensure defense in depth but may involve the use of SSCs that are neither SR nor risk significant. In such a case, the integrated decision process panel (IDPP) would classify the SSCs as safety significant and NSRST because they perform functions required for DID adequacy. Special treatment requirements for NSRST SSCs include the setting of performance requirements for SSC reliability, availability, and capability and any other treatments the IDPP responsible for evaluating the adequacy of DID deems necessary. To this end, the IDPP could recommend availability controls similar to those associated with RTNSS developed for previous LWR design certifications.

Further, previous design certifications (e.g., economic simplified boiling water reactor (ESBWR) and AP1000) ultimately included these RTNSS controls in their FSARs rather than in TS. COL applicants and holders have incorporated this information in their TRMs or similar applicant- or licensee-controlled documents such as Availability Control Documents.

Non-LWR applicants may include both passive and other systems that perform functions that are not safety related but warrant inclusion of special treatment as part of system design. As noted above, if the IDPP identifies availability controls similar to those found in the LWR AP1000 and ESBWR design certifications, the applicant may develop RTNSS-type controls for its non-LWR application.

Staff Review Guidance

Staff review of non-LWR designs following the LMP process in which the application includes NSRST availability controls similar to those associated with RTNSS for the ESBWR and AP1000 may be informed by NUREG-0800, Section 19.3, “Regulatory Treatment of Nonsafety Systems [RTNSS] for Passive Advanced Light Water Reactors” (Ref. 34).

Additional References for Applicant and Staff Consideration

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both.

- NUREG-1430, “Standard Technical Specifications Babcock and Wilcox Plants, Revision 5,” September 2021 (Ref. 35)

- NUREG-1431, “Standard Technical Specifications Westinghouse Plants, Revision 5,” September 2021 (Ref. 36)

- NUREG-1432, “Standard Technical Specifications Combustion Engineering Plants, Revision 5,” September 2021 (Ref. 37)

- NUREG-1433, "Standard Technical Specifications General Electric Plants, BWR/4, Revision 5," September 2021 (Ref. 38)

- NUREG-1434, "Standard Technical Specifications General Electric Plants, BWR/6, Revision 5," September 2021 (Ref. 39)

- NUREG-2194, "Standard Technical Specifications Westinghouse Advanced Passive 1000 (AP1000) Plants," April 2016 (Ref. 40)

These Commission papers and their associated SRMs describe the implementation of controls for RTNSS:

- SECY-94-084, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs" (Ref. 41), and its associated SRM (Ref. 42).

- SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs" (Ref. 43), and its associated SRM (Ref. 44).

Quality Assurance Plan

Overview – Application Guidance

Applicants for non-LWR licenses, permits, or certifications are required to provide a description of their quality assurance plans as part of their applications. Depending on whether the application is for a CP, OL, COL, DC, SDA, or ML, the scope of the quality assurance plan will vary with the scope of activities covered by the application. For example, a quality assurance plan description for a CP application should cover the design, fabrication, construction, post-construction, and pre-operational testing activities. A quality assurance plan description for an OL should describe the operational activities, and a quality assurance plan description for a COL should cover the scope of both CP and OL plans. The NRC expects the quality assurance plan description (QAPD) to be a standalone document that may be submitted by applicants as a topical report and incorporated by reference into the SAR.

Additional insights regarding the implementation of quality assurance is available for users considering the incorporation of legacy fuel data to perform fuel qualification. Specifically, the NRC reviewed and approved a quality assurance program plan (QAPP) developed by Argonne National Laboratory (ANL) (see: ANL/NE-16/17, Revision 2, "Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification" (Ref. 45) to provide adequate QA controls to validate key legacy nuclear fuel developmental information and plant data for use by potential developers of new reactor design applications.[7] The information in the ANL QAPP was generated, characterized, and summarized at historic Department of Energy (DOE) research and development facilities. The ANL legacy metallic fuel data qualification program collected, maintained, and qualified metallic fuel data generated through the Sodium Cooled Fast Reactor (SFR) program. The ANL QAPP establishes a general process to determine the use of the historical information and legacy metallic fuel data for a future end user's licensing activities

[7] The staff's ANL/NEI-16/17 safety evaluation can be found at "Safety Evaluation for Argonne National Laboratory Quality Assurance Program Plan for Sodium Fast Reactor Metallic Fuel Data Qualification," March 3, 2020 (ADAMS Accession No. ML20054A297).

using the standards and QA requirements of the ASME Nuclear Quality Assurance (NQA)-1-2008/2009 Standard, which the NRC staff has endorsed as an acceptable method of meeting 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.” An applicant seeking to utilize data developed outside its test program (such as the legacy fuel data example cited above) would need to justify the quality assurance pedigree of the data in some fashion, in addition to justifying the applicability of the data to its specific design and plant operational envelope.

Staff Review Guidance

The staff’s review will be consistent with the guidance provided in NUREG-0800, Section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permits, and New License Applicants” (Ref. 46), since quality assurance plans for non-LWR applications are primarily programmatic and not technology specific. Although there may be some guidance in NUREG-0800, Section 17.5, that specifically addresses LWR-related requirements, the staff should consider these requirements and associated acceptance criteria within the context of applicability to the applicant’s specific reactor technology. For example, reference to specific General Design Criteria (GDC) in 10 CFR Part 50, Appendix A, or Advanced Reactor Design Criteria found in RG 1.232 may not be applicable to a specific non-LWR applicant because such an applicant is required to provide principal design criteria that are specific to the design in the application. (See DG 1404, “Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors,” for guidance related to principal design criteria.) For quality assurance associated with non-safety-related SSCs that are risk significant (i.e., NSRST classification using the LMP process), additional staff review guidance in NUREG-0800, Section 17.4, “Reliability Assurance Program (RAP)” (Ref. 47), may be appropriate.

Additional References for Applicant and Staff Consideration

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both.

- RG 1.28, “Quality Assurance Program Criteria (Design and Construction)” (Ref. 48)
- RG 1.30, “Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment (Safety Guide 30)” (Ref. 49)
- RG 1.33, “Quality Assurance Program Requirements (Operation)” (Ref. 50)
- RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants” (Ref. 51)
- ANL/NE-16/17, Revision 2, “Quality Assurance Program Plan for SFR Metallic Fuel Data Qualification” (Ref. 52)

Fire Protection Program (Design)

Overview – Application Guidance

Non-LWR applicants must describe the features included in the design for prevention, detection, and suppression of fire hazards for their proposed facilities, as well as the design of the fire protection features that are determined appropriate for their proposed facilities. The analysis of the risk from both internal and external fire hazards is addressed in the guidance for applicants using the LMP process in DG 1404, which endorses NEI 21-07, Revision 1. In addition, the application must describe the results of the fire hazard analysis, including designation of fire zones, fire areas, design of fire barriers, penetration seals, and fire doors, as well as the fire protection detection, suppression, and mitigation systems.

The fire protection design features will also be dependent upon the coolant used in the design. For example, in general, designs that utilize water for the reactor coolant must comply with the fire protection requirements in GDC 3 in 10 CFR Part 50, Appendix A, and 10 CFR 50.48, "Fire Protection." A design that uses an inert gas for the reactor coolant should comply with a principal design criterion (PDC) for fire protection similar to GDC 3. In addition, for designs that utilize coolants other than water or inert gas, such as liquid metal or molten salt, those portions of the design not containing liquid metal or molten salt should also comply with the requirements in an appropriate PDC similar to GDC 3 and the applicable requirements of 10 CFR 50.48 (see Appendix B of this ISG for applicability of regulations to non-LWRs). However, for designs that do not utilize water or inert gas as the coolant, design specific fire protection features will be necessary to address the unique fire hazards posed by these coolants. The hazards can include adverse impacts on surrounding SSCs from leakage of the coolant and fires initiated by the leaking coolant and chemical reactions with surrounding materials, including the generation of flammable gas. The applicant will need to describe and justify the fire protection design features proposed for use when a coolant other than water or inert gas is used. For additional information see RG 1.189, "Fire Protection for Nuclear Power Plants" (Ref. 53).

Staff Review Guidance

The staff's review may be informed by guidance provided in NUREG-0800, Section 9.5.1.1, "Fire Protection Program," (Ref. 54). The review guidance addresses fire protection programs associated with fire protection features included in water or inert gas cooled advanced reactor facilities and those portions of other facilities that contain only water or inert gas.

For reactor designs that do not use water or inert gas as a coolant, the reviewer needs to review the proposed fire protection features and determine whether the features adequately address the unique hazards presented by the coolant. For example, does the design include features (1) to preclude the coolant from coming in contact with water and concrete in the event of a leak (to avoid possible chemical reactions and the production of flammable gas), (2) to suppress any fire initiated by a leak (e.g., to avoid the generation of toxic combustion products and the spread of radiation), (3) to detect fires initiated by coolant leaks, and (4) to contain the volume of coolant available to leak (to keep the coolant from spreading and initiating fires or damage in other areas).

Typical features used in designs containing liquid metal or molten salt coolants include:

- Steel liners in compartments containing liquid metal or molten salt
- Inert atmospheres in areas containing radioactive liquid metal or molten salt
- Features (e.g., steel lined compartments, steel catch pans) that can hold the entire inventory of liquid metal or molten salt available to leak
- Fire suppression decks to cover the catch pans to limit air ingress
- Fire suppression systems in areas containing non-radioactive liquid metal or molten salt
- Fire detection systems capable of detecting and annunciating the presence of liquid metal or molten salt aerosols and combustion products
- Ventilation systems to remove smoke and combustion products

Additional References to Historical Examples of Proposed Fire Protection Features for Designs Not Using Water or Inert Gas as the Coolant

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both.

- The staff review of the proposed Principal Design Criteria relating to the sodium fire protection system for the Clinch River Breeder Reactor is documented in NUREG-0968, "SER Related to the Construction of the Clinch River Breeder Reactor Plant" (Ref. 55). Section 9.13.2, "Sodium Fire Protection System," may provide a useful example of fire protection considerations for designs not using water or inert gas for coolant.
- The staff views on the fire protection features for the Power Reactor Innovative Small Module Reactor and intended to comply with General Design Criterion 3, "Fire Protection," can be found in NUREG-1368, "Preapplication SER for the Power Reactor Innovative Small Module (PRISM) Liquid-Metal Reactor" (Ref. 56), Section 9.8, "Plant Fire Protection System." The description of these features and the staff views on the information needing further development for a PRISM application may provide a useful example of fire protection considerations for designs not using water or inert gas for a coolant.
- ANS Standard 54.8, "Liquid Metal Fire Protection in LMR Plants," November 1988 (Ref. 57). An applicant who wishes to follow ANS 54.8 for the fire protection design of a reactor that does not use water or an inert gas as the coolant should describe in the application why that standard applies to the proposed design and why the standard is adequate to comply with the proposed PDC relevant to the coolant. The NRC staff will consider applicability of ANS 54.8 on a case-by-case basis.

While these historical examples illustrate possible approaches to fire protection for designs not using water or inert gas as the coolant, they are neither definitive nor controlling for any current design.

Probabilistic Risk Assessment

Overview – Application Guidance

Applicants for non-LWR licenses, permits, or certifications may be using risk-informed, performance-based methodologies to develop their safety analysis reports. These methodologies may rely on probabilistic risk assessments (PRAs) used to develop risk significance insights during the design process. NRC regulations in 10 CFR Part 52 require the use of PRAs.[8] The NRC endorsed a non-LWR PRA standard and related peer review standard in RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light Water Reactor Risk-Informed Activities," Revision 0, March 2022 (Ref. 58) which was issued for trial use. In addition, although not required in 10 CFR Part 50, these proposed non-LWR PRA standards may be used by applicants for Part 50 CPs and OLs for non-LWR designs.

As noted in DG-1404 the LMP-based approach is based on the use of PRA. Further guidance on how the PRA is used to develop portions of the application can be found in the DG-1404, and NEI 21-07, Revision 1.

Staff Review Guidance

During staff reviews of non-LWR applications using risk-informed, performance-based methodologies that include the use of PRAs, the staff should determine whether non-LWR PRAs conform with the guidance contained in RG 1.247 (for trial use). RG 1.247 endorses with exceptions and clarifications ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants" (Ref. 59) and also endorses with no exceptions NEI 20-09, Revision 1, "Performance of PRA Peer Reviews Using the ASME/ANS Advanced Non-LWR PRA Standard" (Ref. 60). To the extent a non-LWR PRA departs from the guidance in RG 1.247, the staff should evaluate the PRA on a case-by-case basis.

Emergency Preparedness Plan

Overview – Application Guidance

The ongoing "Emergency Preparedness Requirements for Small Modular Reactors and Other New Technologies" rulemaking would amend NRC's emergency preparedness (EP) regulations under 10 CFR 50.47 and Appendix E to add a new alternative framework for EP requirements for small modular reactors (SMRs) and other new technologies (ONTs) such as non-light-water reactors and non-power production or utilization facilities. In January 2022, the NRC staff submitted SECY-22-0001, "Rulemaking: Final Rule Emergency Preparedness for Small Modular Reactors and Other New Technologies (RIN 3150-AJ68; NRC-2015-0225)" (Ref. 61) to the Commission to request approval of a final rule. The rule would provide an optional performance-based, consequence-oriented, and technology-inclusive approach that would include a scalable plume exposure pathway emergency planning zone. This alternative approach would be

[8] The staff notes that in SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150 AI66)," (ADAMS Accession No. ML21158A055), the NRC staff proposes to amend 10 CFR 50.34(a) and 10 CFR 50.34(b) to require CP and OL applicants, respectively, to submit a description of a plant-specific PRA and its results.

available for applicants for new NRC licenses for SMRs and ONTs and would reduce the regulatory burden related to the exemption process.

Staff Review Guidance

Current staff review guidance for emergency planning is provided in NUREG-0800, Section 13.3, “Emergency Planning” (Ref. 62), and, although LWR-based, may provide some useful insights for reviewing non-LWR applications.

Additional References for Applicant and Staff Consideration

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both. *(Note: Appendix D of this document, “Draft Advanced Reactor Content of Application Project (ARCAP) Guidance Documents Under Development as of November 2022,” provides a reference that is under development in this area.)*

- NUREG-0396, “Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants” (Ref. 63)

- NUREG-0654, “Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (FEMA-REP-1)” (Ref. 64)

- RG 1.101, “Emergency Planning and Preparedness for Nuclear Power Reactors” (Ref. 65)

Security Plans

Overview – Application Guidance

The NRC is currently developing a limited scope rule on physical security (RIN 3150-AK19) that is proposed to apply to reactors that meet a certain criterion. The staff plans to develop additional guidance (for the contents of application) in conjunction with the development of the rule, and the guidance in this area will be updated as appropriate.

The current security guidance applies in the absence of a final limited scope security rule or, should the Commission issue the rule, for a reactor that does not meet the criterion ultimately approved. In addition to a physical security plan, an applicant is required to develop training and qualification plan, safeguards contingency plan, access authorization, and cyber security plan (cyber security plan discussion can be found below).

Staff Review Guidance

Current staff review guidance associated with physical security is provided in NUREG-0800, Section 13.6, “Physical Security” (Ref. 66), which establishes criteria that the NRC staff uses in evaluating whether an applicant or licensee meets NRC regulations to construct and operate nuclear power plants. Although LWR-based, NUREG-0800, Section 13.6, may provide useful insights for reviewing non-LWR applications. As appropriate, NUREG-0800, Section 13.6, points to other relevant NUREG-0800, Sections including:

- NUREG-0800, Section 13.6.1, “Physical Security – Combined License and Operating Reactors,” (Ref. 67)

- NUREG-0800, Section 13.6.2, “Physical Security – Design Certification,” (Ref. 68)

- NUREG-0800, Section 13.6.4, “Access Authorization Operational Program,” (Ref. 69)

Additional References for Applicant and Staff Consideration

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both. *(Note: Appendix D of this document notes references that are under development in this area.)*

- RG 5.59, “Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance,” (Ref. 70)

- RG 5.69, “Guidance for the Application of the Radiological Sabotage Design-Basis Threat in the Design, Development, and Implementation of a Physical Security protection Program that Meets 10 CFR 73.55 Requirements” (Ref. 71)

- RG 5.81, “Target Set Identification and Development for Nuclear Power Reactors,” Revision 1 (Ref. 72)

- RG 5.54, “Standard Format and Content of Safeguards Contingency Plans for Nuclear Power Plants, Revision 1 (Ref. 73)

- RG 5.66, “Access Authorization Program for Nuclear Power Plants,” (Ref. 74)

- RG 5.75, “Training and Qualification of Security Personnel at Nuclear Power Facilities (Ref. 75)

- RG 5.76, “Physical Protection Programs at Nuclear Power Reactors,” (Ref. 76)

- RG 5.77, “Insider Mitigation Program,” (Ref. 77)

- RG 5.79, “Protection of Safeguards Information,” (Ref. 78)

- SECY-22-0072, “Proposed Rule: Alternative Physical Security Requirements for Advanced Reactors (RIN 3150-AK19) (Ref. 79)

Cyber Security Plan

Overview – Application Guidance

Applicants must provide a cyber security plan to the NRC for review to meet the requirements of 10 CFR 73.54, “Protection of Digital Computer and Communication Systems and Networks.” The staff has determined that no additional guidance for non-LWR applications in this area is now necessary because the existing guidance is adequate to guide an applicant’s preparation of the cyber security plan. Guidance for developing a cyber security plan is provided in RG 5.71, "Cyber Security Programs for Nuclear Facilities" (Ref. 80).

Staff Review Guidance

The NRC evaluates the applicant's/licensee's plan to provide high assurance that the digital computer and communication systems and networks associated with safety, security, and emergency preparedness functions, as well as support systems and equipment, which if compromised, would adversely impact safety, security, or emergency preparedness functions, are adequately protected against cyber-attacks. When evaluating the cyber security plan, the staff should consider the review guidance in NUREG-0800, Section 13.6.6, "Cyber Security Plan" (Ref. 81).

Special Nuclear Material (SNM) Control and Accounting

Overview – Application Guidance

A non-LWR power reactor applicant must provide information in its application about the material control and accounting (MC&A) program to meet the requirements of 10 CFR Part 74, "*Material Control and Accounting of Special Nuclear Materia*l." In addition, since an MC&A program is a system of material control measures and material accounting measures to prevent, deter, and detect unauthorized removal or misuse of special nuclear material (SNM), the applicant's program should be developed and implemented prior to SNM receipt, and be maintained as long as any SNM is on site.

MC&A guidance documents were developed primarily for LWRs; however, non-LWR applicants may find useful guidance in the documents provided below for developing their programs.

In the absence of specific MC&A program guidance for all potential non-LWR technologies, the NRC encourages applicants to engage with staff during pre-application to discuss its plans for developing MC&A programs specific to their reactor designs.

Staff Review Guidance

Current staff review guidance associated with material control and accountability is provided in NUREG-0800, Section 13.6, which establishes criteria that the NRC staff uses in evaluating whether an applicant or licensee meets NRC regulations to construct and operate nuclear power plants. Although LWR-based, NUREG-0800, Section 13.6, may provide useful insights for reviewing non-LWR applications.

Additional References for Applicant and Staff Consideration

The following additional guidance document may provide useful information to an applicant, the NRC staff, or both.

- Regulatory Guide 5.29, "Special Nuclear Material Control and Accounting Systems for Nuclear Power Plants," Revision 2 (Ref. 82)

- For Category I facility NUREG 1280, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment; 10 CFR Part 74

Amendment E," Revision 1 (Ref. 83)

- For Category II facility NUREG-2159, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control Plan Required for Special Nuclear Material of Moderate Strategic Significance," Revision 1 (Ref. 84)

- For Category III facility NUREG-1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities," Revision 2 (Ref. 85)

Fire Protection Program (Operational)

Overview – Application Guidance

The fire protection program description that a non-LWR applicant submits will include operational aspects. The guidance for developing application content for fire protection operational programs is described in DANU-ISG-2022-09, "Risk-informed, Performance-Based Fire Protection Program (for Operations)" (Ref. 86). DANU-ISG-2022-09 refers to National Fire Protection Association (NFPA) standards that the NRC has not endorsed for use for non-LWR designs. An applicant seeking to apply these NFPA standards to a non-LWR design should do so within the limitations and caveats identified in DANU-ISG-2022-09. Such an applicant should engage with the NRC staff during preapplication review to identify issues unique to the use of these NFPA standards for the applicant's design.

Staff Review Guidance

The staff review guidance for fire protection operational programs for non-LWRs is also described in DANU-ISG-2022-09.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU-ISG-2022-09 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references.)*

- RG 1.205, Revision 2, "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants"

- RG 1.189, Revision 4, "Fire Protection for Nuclear Power Plants"

- RG 1.232 "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors"

- RG 1.247 (for Trial Use), "Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities"

- NFPA 804, "Standard for Fire Protection for Advanced Light Water Reactor Electric Generating Plants"

- NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants"
- NFPA 806, "Performance-Based Standard for Fire Protection for Advanced Nuclear Reactor Electric Generating Plants Change Process"

Radiation Protection Program

Overview – Application Guidance

The information that is typically presented in an application includes a discussion of how radiation protection practices are incorporated into operational programs and plans and design decisions; a general description of the radiation source terms; radiation protection design features, including a description of plant shielding, ventilation systems, and area radiation and airborne radioactivity monitoring instrumentation; designation of radiation areas; a dose assessment for operating and construction personnel; and a discussion of the design of the health physics facilities. Specifically, applicants should provide information on facility and equipment design, including shielding, planning and procedures programs, and techniques and practices employed by the applicant to meet the radiation protection standards set forth in 10 CFR Part 20, and to be consistent with the guidance given in the appropriate regulatory guides, where the practices set forth in such guides are used to implement NRC regulations.

The guidance for non-LWR applicants using the LMP process is contained in the TICAP DG 1404, which endorses NEI 21-07, Revision 1; however, the LMP process focuses on radiation exposure to the public due to AOOs, DBEs, DBAs, and BDBEs, and must be supplemented with guidance for maintaining radiation exposures for facility personnel during construction activities, normal plant operations, and in response to AOOs and accident conditions, within regulatory limits. Many radiation protection (RP) programs are capable of maintaining radiation exposures within regulatory limits; among these, an applicant may choose to adopt the RP program described in NEI 07-03A, Revision 0, "Generic FSAR Template Guidance for Radiation Program Description" (November 24, 2008) (Ref. 87).

NEI 07-03A, Revision 0, "Generic FSAR Template Guidance for Radiation Program Description", is a complete generic radiation protection (RP) program description for use with combined license (COL) applications. NEI 07-03A is not applicable to the review and issuance of construction permits or operating licenses. While the NRC staff has not endorsed NEI 07-03A, it has approved the NEI 07-03A RP program template via safety evaluation and NEI 07-03A is similar to an approved topical report. Accordingly, an applicant who wishes to adopt the NEI 07-03A RP program template to maintain occupational and public radiation exposures within regulatory limits and as low as is reasonably achievable should explain why the RP program template applies to its proposed facility, including how the conditions for use of the template, if any, are satisfied, and add any information the RP program template identifies as an applicant's responsibility.

Staff Review Guidance

Current staff review guidance for radiation protection programs can be found in NUREG-0800, Section 12.5, "Operational Radiation Protection Program" (Ref. 88), and, although LWR-based, may provide some useful insights for reviewing non-LWR applications. The review will focus on the radiation protection program associated with the specific design considerations of the proposed reactor facility to ensure occupational and public radiation exposures are maintained within regulatory limits.

Additional References for Applicant and Staff Consideration

The following additional guidance document may provide useful information to an applicant, the NRC staff, or both.

- RG 1.206, "Combined License Applications for Nuclear Power Plants," Part I, Standard Format and Content for Combined License Applications, Section C.I.12, Radiation Protection (Ref. 89)

Offsite Dose Calculation Manual

Overview – Application Guidance

The offsite dose calculation manual (ODCM) is an example of one of the documents that may be identified in the administrative controls section of the Technical Specifications (TS) that is used to develop reports required to be submitted to the NRC but is not required to be submitted as part of an application. Other examples from LWR-based TSs include the core operating limits report and reactor coolant system pressure and temperature limits report. These documents are also referred to in the ARCAP TSs guidance document DANU-ISG-2022-08, "Risk-Informed Technical Specifications"; however, there is no prescribed guidance provided in that ARCAP guidance on the format and content for an ODCM.

For COL applicants, guidance developed in RG 1.206 considered the ODCM as part of the Process and Effluent Sampling and Monitoring Program. SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, an Acceptance Criteria," (Ref. 90), and its associated SRM (Ref. 91) indicated that ITAAC would be unnecessary for an operational program other than Emergency Planning (EP) if an applicant fully described the program and its implementation in the FSAR. Under that approach, the FSAR would include implementation milestones for the program. If the NRC determined to grant the COL, it would include a condition requiring implementation tied to an FSAR milestone date. Although no regulation explicitly requires an ODCM, if an applicant relies on an ODCM to satisfy NRC requirements, for example, as part of the Process and Effluent and Monitoring Program, the applicant should fully describe the ODCM and its implementation in the FSAR.

A template for the ODCM was developed in NEI 07-09A "Generic FSAR Template Guidance for Offsite Dose Calculation Manual Program Description," (Ref. 92), and approved by the NRC for use by COL applicants. As the guidance provided in NEI 07-09A on ODCM format and content was LWR-based, the final ODCM format and content for specific non-LWR reactor technologies may differ. The NEI 07-09A generic template fully describes, at the functional level, elements of the process and effluent monitoring and sampling programs required by 10 CFR Part 50, Appendix I, and 10 CFR 52.79(a)(16). While the NRC staff has not endorsed NEI 07-09A, it has approved the NEI 07-09A ODCM template via safety evaluation and NEI 07-09A is similar to an approved topical report. Accordingly, an applicant who wishes to adopt the NEI 07-09A ODCM template should explain why it applies to its proposed facility, including how the conditions for use of the template, if any, are satisfied, and add any information the template identifies as an applicant's responsibility. The adequacy of implementation of the final ODCM will be determined through NRC inspection and oversight activities performed before facility operation begins.

Staff Review Guidance

Current staff review guidance for ODCM can be found in NUREG-0800, Section 11.5, "Process and Effluent Radiological Monitoring Instrumentation and Sampling Systems" (Ref. 93), and, although LWR-based, may provide some useful insights for reviewing non-LWR applications. A description of this program is not required for a CP, DC, SDA, or ML application.

Additional References for Applicant and Staff Consideration

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both.

- NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," Generic Letter 89-01, Supplement No. 1 (Ref. 94)

- RG 1.206, "Combined License Applications for Nuclear Power Plants," Part I, Standard Format and Content for Combined License Applications, Section C.I.16, Technical Specifications (Ref. 95)

Inservice Inspection (ISI)/Inservice Testing (IST)

Overview – Application Guidance

Currently, the requirements for ISI and IST programs are described in 10 CFR 50.55a. Section 50.55a(a)(1)(ii) incorporates by reference specified editions and addenda of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components," Division 1, "Rules for Inspection and Testing of Components of Light-Water-Cooled Plants," with limitations identified in § 50.55a(a)(2). These requirements apply only to LWRs and are based upon standards developed by the ASME. With the increased use of probabilistic risk information in the design and regulation of nuclear power plants, the NRC staff anticipates that applications for future nuclear power plants will include risk-informed ISI and IST programs. The staff has developed guidance in the ISG referenced below that describes the methods acceptable to the NRC staff for the content of an application describing risk-informed ISI and IST programs for a non-LWR design.

The guidance for developing application content for risk-informed ISI and IST programs is described in DANU-ISG-2022-07, "Risk-informed ISI/IST Programs" (Ref. 96).

Staff Review Guidance

The staff review guidance for risk-informed ISI and IST programs can also be found in DANU ISG-2022-07.

Guidance Documents that are Referenced in the ISG

Additional guidance documents referred to in DANU ISG-2022-07 may provide useful information to an applicant, the NRC staff, or both. *(Note that this ISG provides the appropriate context for use of the references and details on how to access these references. The NRC staff notes for the industry guidance document provided below the applicable NRC endorsement document must be considered for any exceptions, clarifications, or additions associated with the use of this guidance document.)*

- RG 1.246, "Acceptability of ASME Code, Section XI, Division 2, 'Requirements for Reliability and Integrity Management (RIM) Programs for Nuclear Power Plants,' for Non-Light Water Reactors"

- RG 1.247 (for Trial Use), "Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities"

- ASME, QME-1, "Qualification of Active Mechanical Equipment Used in Nuclear Facilities," January 2017

- RG 1.100, "Seismic Qualification of Electric and Mechanical Equipment for Nuclear Power Plants"

- RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors"

- ASME, *Boiler and Pressure Vessel Code*, 2019 Edition, Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components," Division 2, "Requirements for Reliability and Integrity Management (RIM) Programs for Nuclear Power Plants"

- ASME, *Boiler and Pressure Vessel Code*, Section III, "Rules for Construction of Nuclear Facility Components," Division 1

- RG 1.87, Revision 2, "Acceptability of ASME Code Section III, Division 5, 'High Temperature Reactors'"

Environmental Report and Site Redress Plan

Application and Staff Review Guidance

The staff has determined that no additional guidance for non-LWR applications in this area is now necessary because the existing guidance is adequate to guide an applicant's preparation of the environmental report.[9] Similarly, existing guidance is adequate to ensure the NRC will satisfy the National Environmental Policy Act of 1969, as amended.

[9] The NRC is developing an advanced reactor Generic Environmental Impact Statement (GEIS) in order to streamline the environmental review process for future advanced reactor environmental reviews. This ISG will be updated to reflect the GEIS for advanced reactors when it becomes available. Information regarding the status of the GEIS for advanced reactors can be found at: https://www.nrc.gov/reactors/new-reactors/advanced/rulemaking-and-guidance/advanced-reactor-generic-environmental-impact-statement-geis.html

Additional References for Applicant and Staff Consideration

The following additional guidance documents may provide useful information to an applicant, the NRC staff, or both.

- RG 4.2, “Preparation of Environmental Reports for Nuclear Power Stations,” (Ref. 97)
- NUREG-1555, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants: Environmental Standard Review Plan (with Supplement 1 for Operating Reactor License Renewal)” (Ref. 98)
- COL/ESP-ISG-026, “Interim Staff Guidance on Environmental Issues Associated with New Reactors” (Ref. 99)
- COL/ESP-ISG-027, “Interim Staff Guidance on Specific Environmental Guidance for Light Water Small Modular Reactor” (Ref. 100)
- COL/ESP-ISG-029, “Environmental Considerations Associated with Micro-reactors” (Ref. 101)

Financial Qualification and Insurance and Liability

Overview

Financial Qualification

Pursuant to 10 CFR 50.33(f) and as reflected in 10 CFR Part 50 Appendix C, “A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses,” an applicant for an initial license under 10 CFR Part 50, with certain exceptions, must demonstrate that it possesses or has reasonable assurance that it can obtain the funds necessary to construct or operate the facility. These requirements also apply to applicants for COLs for new reactors under 10 CFR Part 52, which references the financial qualification requirements in 10 CFR Part 50. In an SRM dated July 14, 2022, (Ref. 102) on SECY-18-0026, Proposed Rule: Financial Qualification Requirements for Reactor Licensing (RIN 3150-AJ43),” the Commission disapproved the draft proposed rule that would have amended these requirements and instead directed the staff to address financial qualifications during the development of 10 CFR Part 53. This ISG will be updated to reflect the Commission direction as reflected in the 10 CFR Part 53 rulemaking effort.

In addition, pursuant to the requirements of 10 CFR 50.33(k)(1), an applicant for an OL or COL for a utilization facility will provide information in the form of a report, as described in 10 CFR 50.75, “Reporting and recordkeeping for decommissioning planning,” indicating how reasonable assurance will be provided that sufficient funds will be available to decommission the facility.

Insurance and Liability

The provisions of the Price-Anderson Act (Section 170 of the Atomic Energy Act of 1954, as amended) and the Commission’s implementing regulations in 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements” (Ref. 103), require, in part, that each holder of an OL or COL issued pursuant to 10 CFR Part 50 or 10 CFR Part 52, respectively, have and maintain financial protection in a specified amount that depends on the number and thermal power of the reactors licensed at a particular site. Additionally, as required by 10 CFR 50.54(w), a power reactor licensee must obtain insurance to stabilize and decontaminate the reactor and the reactor station site in the event of an accident at the licensee's reactor.

In public meetings on this topic, stakeholders (including designers and industry organizations) have indicated that no immediate actions are called for to revise current insurance and liability requirements for new reactor designs. While the NRC does not envision a need for changes to the Price-Anderson Act, guidance updates or rulemaking may be necessary to develop a financial protection framework for non-LWRs, including the licensing of multimodule or multiunit designs and facilities.

On December 9, 2021, the NRC submitted to Congress NUREG/CR-7293, "The Price-Anderson Act: 2021 Report to Congress Public; Liability Insurance and Indemnity Requirements for an Evolving Commercial Nuclear Industry," dated December 2021 (Ref. 104). Section 2.2.1.1 of the report, "New Nuclear Technologies," provides additional information on emerging reactor technologies and how the Price-Anderson Act may be applied to each. The report concludes:

> Overall, the staff has not identified any information that suggests discontinuing the Price- Anderson Act provisions would be warranted based on NRC's public health and safety mission. The NRC staff therefore recommends that the same amount, type, and terms of public liability protection be provided for future and existing licensees.

Financial Qualification – *Application Guidance*

RG 1.206 Section C.1.1, "General and Financial Information," Revision 1, provides application content guidance that generally applies to LWR and non-LWR technologies. Additional guidance can be found in RG 1.159, "Assuring the Availability of Funds for Decommissioning Nuclear Reactors," Revision 2, dated October 2011 (Ref. 105), and NUREG 1577, "Standard Review Plan on Power Reactor Licensee Financial Qualifications and Decommissioning Funding Assurance," Revision 1, dated February 1999 (Ref. 106). The staff notes that the decommissioning guidance found in these guidance documents are based on LWR technologies. Non-LWR applicants are encouraged during the preapplication phase to discuss with the staff its plans for developing decommission funding estimates for their specific non-LWR technology.

Financial Qualification – *Staff Review Guidance*

The staff should confirm that the CP, OL, or COL, application includes the material that is referenced in this section to ensure the underlying requirements are met.

Insurance and Liability – *Application Guidance*

RG 1.206, Section C.2.19, "Nuclear Insurance and Indemnity," Revision 1, provides application content guidance that generally applies to LWR and non-LWR technologies. If an applicant requests a 10 CFR Part 70 license as part of a CP application to allow for receipt of fuel onsite before an OL is granted, insurance and indemnity requirements may apply.

Insurance and Liability – *Staff Review Guidance*

The staff should confirm that the OL or COL application includes the material that is referenced in this section to ensure the underlying requirements are met.

<u>Fitness for Duty Program</u>

Overview – Application Guidance

An applicant for a CP or COL that intends to implement a fitness-for-duty (FFD) program that meets the requirements of 10 CFR Part 26, “Fitness for Duty Programs,” Subpart K, “FFD Program for Construction,” for the individuals specified in 10 CFR 26.4(f) must provide a description of the FFD program and its implementation as part of its CP or COL application. The staff has determined that no additional guidance in this area for non-LWR CP and COL applications is necessary because the existing guidance in RG 5.84, “Fitness-For-Duty Programs at New Reactor Construction Sites,” (Ref. 107) is adequate to guide an applicant’s preparation of its Subpart K FFD program description.

For the individuals specified in 10 CFR 26.4(e) and (g), the CP or COL applicant must implement an FFD program during construction that meets all Part 26 requirements except Subparts I, “Managing Fatigue,” and K. A CP or COL applicant that elects not to implement a Subpart K FFD program for the individuals specified in 10 CFR 26.4(f) must include those individuals in the FFD program for the individuals specified in 10 CFR 26.4(e) and (g). Notwithstanding which of the approaches the COL applicant intends to take during construction, the COL applicant must include in its application a description of the FFD program for construction and its implementation.

Before it receives special nuclear material in the form of fuel assemblies, holders of an OL or COL must implement an FFD program that meets all Part 26 requirements except Subpart K. This COL applicant must include in its application a description of this FFD program and its implementation. The existing guidance in RG 5.73, “Fatigue Management for Nuclear Power Plant Personnel,” (Ref. 108) can guide an applicant’s preparation of its description of its fatigue management program under Part 26, Subpart I, and RG 5.89, “Fitness-For-Duty Programs For Commercial Power Reactor and Category I Special Nuclear Material Licensees,” (Ref. 109) can guide an applicant’s preparation of its description of its methods for collecting urine specimens under Part 26, Subpart E, “Collecting Specimens for Testing,” and reviewing test results under Part 26, Subpart H, “Determining Fitness-for-Duty Policy Violations and Determining Fitness.”

Staff Review Guidance

When evaluating the applicants FFD program, the staff should consider the review guidance in NUREG-0800, Section 13.7.1, “Fitness for Duty -Operational Program,” (Ref. 110), and NUREG-0800, Section 13.7.2, “Fitness for Duty – Construction” (Ref.111).

<u>Facility Safety Program</u>

Overview – Application and Staff Review Guidance

This section is reserved.[10]

[10] There are currently no requirements for the development of a facility safety program in 10 CFR Part 50 or Part 52. However, the NRC staff is developing proposed requirements for a facility safety program as part of the preparation

Inspections, Tests, Analysis, and Acceptance Criteria (ITAAC)

Overview – Application Guidance

Applicants for COLs, DCs, and MLs in accordance with 10 CFR Part 52 are required to provide the proposed inspections, tests, and analysis that must be performed, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria are met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC regulations. Applicants for CPs and OLs in accordance with 10 CFR Part 50 are not required to provide ITAAC. Instead, guidance for the post-construction inspection testing and analysis program for non-LWR CP and OL applicants is provided in DANU-ISG-2022-06, "Chapter 12 – 'Post Construction Inspection, Testing, and Analysis Program.'"

Staff Review Guidance

Guidance for staff review of ITAAC submitted in a Part 52 application is in NUREG-0800, Section14.3, "Inspections, Tests, Analyses, and Acceptance Criteria" (Ref. 112).

Aircraft Impact Assessment

Overview – Application Guidance

10 CFR 50.150 requires the following:

- 10 CFR 50.150(a)(1) requires each applicant under Part 50 or Part 52 to perform a design-specific assessment of the effects on the facility of the impact of a large commercial aircraft, unless the application references a license or certification for which a design-specific approval has been performed. Using realistic analysis, the applicant shall identify and incorporate into the design those design features and functional capabilities to show that, with reduced use of operator actions: (1) the reactor core remains cooled, or the containment remains intact; and (2) spent fuel cooling or spent fuel pool integrity is maintained.

- 10 CFR 50.150(b) requires that the preliminary or final safety analysis report must include a description of (1) the design features and functional capabilities identified in 10 CFR 50.150(a)(1), and (2) how the design features and functional capabilities identified in 10 CFR 50.150(a)(1) meet the assessment requirements in 10 CFR 50.150(a)(1).

Therefore, 10 CFR 50.150 requires applicants to perform the aircraft impact assessment at the CP stage as well as other licensing stages and include the required information at these licensing stages based on the level of design information available at the time. The staff has determined that no additional guidance for non-LWR OL and COL applications in this area is now necessary because the existing guidance is adequate to guide an applicant's preparation of

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of 10 CFR Part 53. Should the Commission direct the NRC staff to implement requirements for a facility safety program in Part 53, elements may be incorporated into specific Part 50 or Part 52 regulations. The need for application and NRC staff review guidance in this area is dependent on the implementation of Part 53.

the aircraft impact assessment. See RG 1.217, Revision 0, "Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts," (Ref. 113), which endorses the guidance in NEI 07-13, Revision 8, "Methodology for Performing Aircraft Impact Assessments for New Plant Designs," (Ref. 114), as an acceptable method for use in satisfying the NRC requirements in 10 CFR 50.150(a) regarding the assessment of aircraft impacts for new nuclear power reactors.

Staff Review Guidance

The staff should review the information contained in the application and reach conclusions as to whether the applicant has: (1) adequately described design features and functional capabilities in accordance with 10 CFR 50.150(b); and (2) conducted an assessment reasonably formulated to identify design features and functional capabilities to show, with reduced use of operator action, that the facility can withstand the effects of a large commercial aircraft impact.[11] The staff should consider the review guidance in NUREG-0800, Section 19.5, "Adequacy of Design Features and Functional Capabilities Identified and Described for Withstanding Aircraft Impacts," (Ref. 115) and RG 1.217, Revision 0, which endorses the guidance in NEI 07-13, Revision 8, as an acceptable method for use in satisfying the NRC requirements in 10 CFR 50.150(a) regarding the assessment of aircraft impacts for new nuclear power reactors. When considering the review guidance, the staff should note that the guidance is based on traditional LWR technologies. For non-LWRs, a preapplication discussion with the applicant could aid in addressing the following issues:

- SECY-11-0112, "Staff Assessment of Selected Small Modular Reactor Issues Identified in SECY-10-0034," (Ref. 116), Enclosure 5, "Aircraft Impact Assessments for Small Modular Reactors," provides considerations for aircraft impact assessments for non-LWRs. This enclosure notes that the four functions identified in 10 CFR 50.150(a)(1) are applicable to LWRs and may not be applicable to non-LWR reactor designs or may have to be supplemented by other key functions. When reviewing non-LWR designs, the staff will evaluate the applicability of the acceptance criteria set forth in the aircraft impact rule and the possible need for other criteria. As noted in the statements of consideration for 10 CFR 50.150 (74 FR 28146, June 12, 2009) (Ref. 117), if necessary, the staff will issue exemptions and impose supplemental criteria to be used in the aircraft impact assessment for such non-LWR designs.

  SECY-11-0112 also describes areas for additional staff consideration should an application include the ability to produce process heat for industrial use. In such cases the staff should include the impacts resulting from events at the industrial facility associated with the reactor, including aircraft impacts, as part of the external hazards analysis and the siting evaluation.

- SECY-20-0093, "Policy and Licensing Considerations Related to Micro-Reactors," (Ref. 118) Enclosure 1 includes a discussion of aircraft impact assessments. This enclosure includes the following considerations:

  > From a consequence perspective, the staff expects micro-reactors to resemble nonpower reactors more closely than large LWRs. Further, the site footprint of micro-reactors is likely to be substantially smaller than that of the existing power reactor fleet and the new reactors envisioned when the NRC promulgated the aircraft impact rule. Some micro-reactors might

[11] Consideration of Aircraft Impacts for New Nuclear Power Reactors, 74 FR 28120 (June 12, 2009).

also be located underground, which could prevent a large commercial aircraft from striking safety-significant portions of a facility. A holistic risk-informed consideration of design-specific features, including the potential consequences of an aircraft impact, could provide a basis for meeting the underlying purpose of the rule and would be consistent with the Statements of Consideration, which stated that the NRC may need to issue exemptions and impose supplemental criteria for aircraft impact assessments of non-LWRs. Provided a micro-reactor applicant can make a case for demonstrating compliance with the rule, the staff expects that existing regulatory processes are sufficient to address micro-reactor applications in the near term.

The staff should note that the aircraft impact rule does not require that the actual aircraft assessment be submitted to the NRC. Therefore, the NRC will address the adequacy of the aircraft impact assessment through an inspection of that assessment. However, the licensee is expected to use the results of the aircraft impact assessment to provide the information identified in NUREG-0800, Section 19.5, in its application.

Performance Demonstration Requirements

Overview – Application Guidance

In 10 CFR 50.43(e), the NRC lists performance demonstration requirements specific to applications under 10 CFR Part 50 and 10 CFR Part 52 for licenses for commercial power facilities that differ significantly from LWR designs licensed before 1997 or use simplified, inherent, passive, or other innovative means to accomplish their safety functions. The regulation in 10 CFR 50.43(e)(1) states that the NRC will approve applications for such a reactor design only if (i) the performance of each safety feature of the design has been demonstrated through either analysis, appropriate test programs, experience, or a combination thereof; (ii) interdependent effects among the safety features of the design are acceptable, as demonstrated by analysis, appropriate test programs, experience, or a combination thereof; and (iii) sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences (including equilibrium core conditions). Alternatively, 10 CFR 50.43(e)(2) allows the testing of a prototype plant over a sufficient range of conditions to meet the testing requirements. The regulation permits an applicant to choose either alternative. Appendix A of this document encourages preapplication engagement in this area to optimize the safety review.

Staff Review Guidance

Discussion of the 10 CFR 50.43(e) requirements can be found in “A Regulatory Review Roadmap for Non-Light Water Reactors” (Ref. 119). The enclosure to the Regulatory Review Roadmap describes nuclear power reactor testing needs and prototype plants for reactor designs subject to § 50.43(e). The stated purpose of the Regulatory Review Roadmap enclosure is to:

- Describe the regulations governing the testing requirements for the licensing, approval, or certification of a proposed standard plant design for advanced reactors.

- Describe the process for determining testing needs to meet the U.S. Nuclear Regulatory Commission's (NRC's) regulatory requirements.

- Clarify when a prototype plant might be needed and how it might differ from the proposed standard plant design.

- Describe licensing strategies and options that include the use of a prototype plant to meet the NRC's testing requirements.

Appendix A of the enclosure to the Regulatory Review Roadmap describes a process for determining testing needs. This appendix is a reprint of SECY-91-074, "Prototype Decisions for Advanced Reactor Designs" (Ref. 120). Appendix B of the enclosure to the Regulatory Review Roadmap, describes options for using a prototype plant in the process of obtaining a design certification or standard design approval. The Regulatory Review Roadmap notes that an applicant's research and development plan is an important part of the overall testing plan. This information is useful for the NRC to be aware of what data may become available for verification and validation of computer models, what test facilities may need to be inspected for quality assurance, and which tests the NRC may wish to observe; it may also help determine what related independent research the NRC may wish to conduct. The results from the research and development programs can be provided in technical reports or within an application, including topical reports.

Nuclear Waste Policy Act

Overview – Application Guidance

Section 302(b) of the *Nuclear Waste Policy Act* of 1982, as amended, states:

> (1)(A) The Commission shall not issue or renew a license to any person to use a utilization or production facility under the authority of section 103 or 104 of the Atomic Energy Act of 1954 (42 USC 2133, 2134) unless –
> (i) such person has entered into a contract with the Secretary under this section; or
> (ii) the Secretary affirms in writing that such person is actively and in good faith negotiating with the Secretary for a contract under this section.
>
> (1)(B) The Commission, as it deems necessary or appropriate, may require as a precondition to the issuance or renewal of a license under section 103 or 104 of the Atomic Energy Act of 1954 (42 USC 2133, 2134) that the applicant for such license shall have entered into an agreement with the Secretary for the disposal of high-level radioactive waste and spent nuclear fuel that may result from the use of such license.

The applicant should briefly discuss how it is meeting the requirements of Section 302(b) of the *Nuclear Waste Policy Act* (NWPA) of 1982 for disposal of high-level radioactive wastes and spent nuclear fuel. This discussion should either provide a letter from the appropriate DOE representative affirming that the applicant is actively and in good faith negotiating a contract for disposal of high-level radioactive waste and spent nuclear fuel under Section 302(b)(1)(A)(i) of the NWPA or the contract numbers for the contract arranged with DOE for return of the material under Section 302(b)(2)(A)(ii) of the NWPA. A letter dated December 16, 2008, titled "Vogtle, Units 3 and 4 – Combined License Application Contract for Disposal of High-Level Radioactive

Waste," (Ref. 121) provides an example of such a letter associated with Section 302(b)(1)(A)(i) of the NWPA. A letter dated November 15, 2022, titled "Additional Information Related to Construction Permit Application – FSAR Chapter 1," (Ref. 122), provides an example of such a letter associated with Section 302(b)(1)(A)(ii) of the NWPA.

Staff Review Guidance

The staff should document in Chapter 1 of the safety evaluation report the applicant's agreement with DOE for the disposal of high-level radioactive waste and spent nuclear fuel that may result from the use of the OL, or COL.

Operational Programs

Overview – Application Guidance

Operational programs are specific programs that are required by regulations. Operational programs include, but are not limited to, Inservice Inspection, Inservice Testing, Fire Protection, Emergency Planning, and Physical Security.

Construction Permit Applications

As noted in Appendix C of this document, this ISG does not provide review guidance on the licensing requirements for byproduct, source, or special nuclear material under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 40, "Domestic Licensing of Source Material"; or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." Appendix C further notes that for some programs such as emergency plans and physical security, less information is required at the CP stage than at the OL or COL stage. If a CP applicant wishes to receive, possess, and use byproduct, source, or special nuclear material before receipt of a 10 CFR Part 50 operating license, the applicant is encouraged to discuss such plans during preapplication interactions with the NRC staff. One purpose of such interactions is to identify the applicable regulations and the type of information that should be included in the descriptions of these programs at the CP stage; another is to identify the implementation milestones for such programs to support receipt, possession, and use of the byproduct, source, or special nuclear material.

Operating License Applications

Operating license applications are required to provide complete descriptions of the operational programs required by regulations. Like a CP application, if an applicant wishes to receive, possess and use byproduct, source, or special nuclear material before receipt of a 10 CFR Part 50 operating license, the applicant is encouraged to discuss such plans with the NRC staff. The applicant may choose to amend the construction permit or seek separate Part 30, 40, or 70 licenses to allow receipt, possession, and use of this material before receiving a 10 CFR Part 50 operating license.

Current NRC practice is to combine existing or requested licenses issued under Parts 30, 40, or 70 with a Part 50 OL, if granted. If the applicant chooses the option to have the Part 30, 40, and 70 licenses issued together with the 10 CFR Part 50 operating license, the review of the operational programs will proceed concurrently and consider and support the issuance of these licenses. Implementation of the appropriate operational programs before issuance of these licenses will be verified via the NRC's licensing and inspection programs.

Combined License Applications

Applicant guidance for operational programs required by regulation can be found in RG 1.206, Revision 1 and includes guidance for materials licensing requirements for the receipt, possession, and use of byproduct, source, and special nuclear material. The guidance notes that the combined license applicant should expect and may propose license conditions allowing the receipt, possession, and use of this material and license conditions associated with the implementation of the operational programs. Should a COL applicant choose to defer a request for a Part 70 license authorizing receipt and possession of special nuclear material in the form of fresh fuel, the Part 70 license may be subsequently added by amendment of the COL, if granted by the Commission.

Staff Review Guidance

Guidance for the review of operational programs is discussed in the appropriate section of this ISG. Should an applicant request a byproduct, source, or special nuclear material license prior to receipt of a 10 CFR Part 50 operating license, NUREG-0800 Section 13.4, "Operational Programs," (Ref. 123) provides insights related to implementation schedules and possible license conditions to support issuance of byproduct, source, or special nuclear material license prior to receipt of a 10 CFR Part 50 operating license.

For combined license applications, NRC staff review guidance associated with the implementation of operational programs to support issuance of a 10 CFR Part 52 combined license that also includes 10 CFR Part 30, 40, and 70 licenses is found in NUREG-0800 Section 13.4.

IMPLEMENTATION

The NRC staff will use the information discussed in this ISG to review non-LWR applications for CPs, OLs, COLs, MLs, SDAs, DCs under 10 CFR Part 50 and 10 CFR Part 52. The staff intends to incorporate this guidance in updated form in the RG or NUREG series, as appropriate.

BACKFITTING AND ISSUE FINALITY DISCUSSION

The NRC staff may use DANU-ISG-2022-1 as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this ISG to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 50.109, "Backfitting," and as described in NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (Ref. 124), nor does the NRC staff intend to use the guidance to affect the issue finality of an approval under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in Management Directive 8.4. If a licensee believes that the NRC is using this ISG in a manner inconsistent with the discussion in this paragraph, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

CONGRESSIONAL REVIEW ACT

Discussion to be provided in the final ISG.

FINAL RESOLUTION

The staff will transition the information and guidance in this ISG into the RG series or NUREG series document, as appropriate. Following the transition of all pertinent information and guidance in this document into the RG or NUREG series, or other appropriate guidance, this ISG will be closed.

ACRONYMS

ALARA	as low as reasonably achievable
ANL	Argonne National Laboratory
ANS	American Nuclear Society
ANSI	American National Standards Institute
AOO	anticipated operational occurrence
ARCAP	advanced reactor content of application project
ASME	American Society of Mechanical Engineers
BDBE	beyond-design-basis event
CDC	complimentary design criteria (CDC)
CFR	*Code of Federal Regulations*
COL	combined license
CP	construction permit
DBE	design basis events
DC	design certification
DID	defense in depth
DG	draft regulatory guide
DOE	U.S. Department of Energy
ESBWR	economic simplified boiling water reactor
ESP	early site permit
FSAR	final safety analysis report
GDC	general design criterion
GEIS	generic environmental impact statement
ISG	interim staff guidance
ISI	inservice inspection
IST	inservice testing
ITAAC	inspections, tests, analysis, and acceptance criteria
ITS	improved technical specifications
LBEs	licensing basis events
LMP	licensing modernization project
LWR	light-water reactor
ML	manufacturing license
NEIMA	Nuclear Energy Innovation and Modernization Act
NQA	Nuclear Quality Assurance
NRC	U.S. Nuclear Regulatory Commission
NSRST	non-safety-related with special treatment

ODCM	offsite dose calculation manual
OL	operating license
ONT	other new technologies
PDC	principal design criteria
PITAP	post-construction inspection, testing and analysis program
PRA	probabilistic risk assessment
QA	quality assurance
QAPD	quality assurance program description
QAPP	quality assurance program plan
RFDC	required functional design criteria
RG	regulatory guide
RTNSS	regulatory treatment of nonsafety systems
SAR	safety analysis report
SDA	standard design approval
SMR	small modular reactor
SNM	special nuclear material
SR	safety-related
SS	safety-significant
STS	standard technical specifications
SRM	staff requirements memorandum
SSC	structure, system, and component
TICAP	technology inclusive content of application project
TRM	technical requirements manual
TS	technical specifications

APPENDICES

A. Pre-Application Engagement Guidance
B. Applicability of NRC Regulations to Non-Light-Water Power Reactors
C. Construction Permit Guidance
D. Draft Advanced Reactor Content of Application Project Guidance Documents Under Development

REFERENCES

1. Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, “Domestic Licensing of Production and Utilization Facilities.”

2 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”

3 U.S. Nuclear Regulatory Commission, Regulatory Guide 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” June 2020, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20091L698).

4 U.S. Nuclear Regulatory Commission, “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness,” December 2016 (ADAMS Accession No. ML16356A670).

5 U.S. Nuclear Regulatory Commission, "NRC Non-Light Water Reactor Near-Term Implementation Action Plans," July 2017 (ADAMS Accession No. ML17165A069).

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15 NEI 21-07, Revision 1, "Technology Inclusive Guidance for Non-Light Water Reactors Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology," February 2022 (ADAMS Accession No. ML22060A190).

16 U.S. Nuclear Regulatory Commission, Draft Regulatory Guide DG 1404, "Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors," (ADAMS Accession No. ML22076A003).

17 U.S. Nuclear Regulatory Commission, DANU-ISG-2022-02, "Chapter 2, 'Site Information,'" (ADAMS Accession No. ML22048B541).

18 U.S. Nuclear Regulatory Commission, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 3.5.1.1, "Internally Generated Missiles (Outside Containment)," Washington, DC

19 U.S. Nuclear Regulatory Commission, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 3.5.1.2, "Internally Generated Missiles (Inside Containment), Washington DC

20 U.S. Nuclear Regulatory Commission, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 3.5.1.3, "Turbine Missiles," Washington, DC

21 U.S. Nuclear Regulatory Commission, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 3.5.3, "Barrier Design Procedures," Washington, DC

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23 U.S. Nuclear Regulatory Commission, NUREG-0800 Section 3.6.2, "Determination of Rupture Locations and Dynamic Effects Associated with the Postulated Rupture of Piping," Washington DC

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29 10 CFR Part 61, "Licensing requirements for land disposal of radioactive waste."

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APPENDIX A - Pre-Application Engagement Guidance

Purpose: The purpose of this Appendix is to provide guidance on the benefits of robust pre-application engagement with advanced reactor[1] developers in order to optimize both safety and environmental application reviews.

Background: In its Policy Statement on the Regulation of Advanced Reactors,[2] the Commission encourages early interactions with advanced reactor developers and prospective applicants as follows:

> To provide for more timely and effective regulation of advanced reactors, the Commission encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs. Such licensing interaction and guidance early in the design process will contribute towards minimizing complexity and adding stability and predictability in the licensing and regulation of advanced reactors.

Further, Section 103 of the Nuclear Energy Innovation and Modernization Act (NEIMA) required the NRC to evaluate (1) options for licensing commercial advanced nuclear reactors including the use of topical reports, standard design approval, and other appropriate mechanisms as tools to introduce stages into the commercial advanced nuclear reactor licensing process; (2) options for improving the efficiency, timeliness, and cost-effectiveness of licensing reviews of commercial advanced nuclear reactors, including opportunities to minimize the delays that may result from any necessary amendment or supplement to an application; and (3) options for improving the predictability of the commercial advanced nuclear reactor licensing process, including the evaluation of opportunities to improve the process by which application review milestones are established and met.

While pre-application interactions are not unique to advanced reactors, the agency recognizes that such interactions may be particularly beneficial with advanced reactor developers because they allow early identification and resolution of technical and policy issues that could affect licensing. Therefore, the NRC staff has identified a set of pre-application activities that, if accomplished, could enable the staff to offer more predictable and shorter schedules during the review of an advanced reactor license application. These pre-application activities are equivalent to a staged licensing approach, where some key elements of an advanced reactor design are considered, and the staff views documented, before the license application is submitted. A topical report review can result in an NRC determination that an approach to a safety question is acceptable if referenced in an application for a reactor with a defined set of characteristics. A staged licensing approach can provide the following advantages:

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[1] Different definitions of the term “advanced reactor” exist. Regardless, for the purpose of this appendix the term “advanced reactor” includes non-light water reactors as well as other technologies.

[2] 73 FR 60612; October 14, 2008

Advantages for Applicants	Advantages for NRC
Enhanced regulatory predictability, reducing project risk.	Greater review efficiency because NRC staff becomes familiar with the design and develops topical report safety evaluations that can be referenced by the application safety evaluation report.
Greater review efficiency because NRC staff becomes familiar with design. Efficiency translates to lower costs and shorter review schedules.	Early public engagement on the attributes of a design, increasing transparency and enhancing public awareness.
Early interactions between the NRC, the applicant, and other agencies that have a role in the environmental review could shorten the licensing review schedule.	NRC staff becomes familiar with new approaches an applicant is considering and unique environmental aspects of a site.
Early engagement with the Advisory Committee on Reactor Safeguards (ACRS) through the review of safety evaluations on topical reports. This early ACRS involvement could improve regulatory reliability and shorten application review times.	Early engagement with the ACRS through the review of safety evaluations on topical reports. This early ACRS involvement could reduce the number of issues addressed during the application review and lessen the effort of application review.

Program for Robust Pre-application Engagement: In response to NEIMA, the NRC staff established generic milestone schedules for licensing reviews.[3] When the generic milestone schedules were established, the NRC staff noted that it would work with each licensee or applicant to establish a specific schedule for each request, which may be shorter or longer than the generic milestone schedule based on the specific needs of the licensee or applicant and the staff's resources. Completion of the applicable items[4] described in the following sections prior to application submittal would allow the NRC staff to establish a review schedule at least 6 months shorter than the generic schedules depending on the complexity of the design.[5] The NRC staff would complete the issuance of the final safety evaluation within that application-specific review schedule as long as the following conditions are met:

- An applicant submits responses to requests for additional information (RAIs) and other necessary information within agreed upon timeframes.

- The applicant makes no substantive changes to the application after submittal.

- For an applicant that participates in pre-application activities, the design does not change significantly between the pre-application activities and the time the application is submitted so that matters considered in pre-application are not adversely impacted.

[3] https://www.nrc.gov/about-nrc/generic-schedules.html
[4] For a design certification, only the safety review items would be applicable. For a combined license application referencing a certified design, the environmental review items would be applicable in addition to safety topics associated with site specific features and any departures to the certified design. For a combined license not referencing a certified design, all the review topics listed would be applicable.
[5] Substantive pre-application engagement of a lesser extent than that described in this paper may result in a shorter review schedule than the NEIMA generic schedules, which would be determined on a case-by-case basis.

In addition to a substantially shorter overall application review, the acceptance review could be shorter if the activities described below are completed before submission of an application. The staff could complete the acceptance review in as short as two weeks[6] if the staff needs only verify that the application includes information presented during pre-application interactions and if only administrative tasks, such as making the application publicly available and issuing a notice of availability, need to be addressed at that time.

A. Topical reports

To support robust preapplication interactions, a prospective applicant should submit topical reports on key topics for review during the pre-application phase. The NRC staff will review these topical reports during the pre-application phase and prepare safety evaluations with findings on the individual technical matters covered in the TR that can be relied on for the application review if the content of the application is consistent with the information approved in the topical report and any limitations and conditions placed on its approval. These topical reports would be beneficial to the review schedule if received early enough to support staff issuance of final staff safety evaluations prior to submittal of an application. Any substantive changes to the design between submission of a topical report and submission of the application, however, could require additional staff review and result in significant changes to the review schedule. The key topics described below are those that should be addressed. At the construction permit stage, the level of design completeness historically included in applications typically did not support staff findings on facility design and security topics, i.e., other than siting issues, and the design may not be complete during the preapplication or permit application review.[7] Historical practice, however, does not restrict an applicant completing discrete portions of the design before submitting a construction permit application. Further, most of the topics below address methods or design fundamentals, and the NRC encourages pre-application engagement in these areas because that would help the staff prepare to review the application by becoming familiar with the fundamental principles of the design and produce schedule efficiencies. Potential candidates for preapplication topical reports include the following:

- **Principal design criteria**

  Under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(3)(i), 10 CFR 52.47(a)(3)(i), and 10 CFR 52.79(a)(4)(i), proposed PDC must be included in an application for a construction permit (CP), design certification (DC), or combined license (COL), respectively. The PDC establish the necessary design, fabrication, construction, testing, and performance of safety significant structures, systems, and components (SSCs). The General Design Criteria (GDC) in 10 CFR Part 50 Appendix A establish minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission and provide guidance to applicants for CPs in establishing PDCs for other types of nuclear power units.

  The NRC staff anticipates non-LWR applicants will review the GDC and the guidance in Regulatory Guide (RG) 1.232, "Guidance for Developing Principal Design Criteria

[6] This schedule is valid only if the applicant submittal meets NRC's requirements for electronic submittal and protection of sensitive information to facilitate release of a public version of the application.

[7] Under 10 CFR 50.35(b), a construction permit constitutes authorization for an applicant to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. An applicant will need to include in the PSAR information sufficient for each design feature or specification for which the applicant requests approval.

for Non-Light-Water Reactors," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17325A611) for appropriate insights to develop their PDC and ensure that necessary safety functions and SSCs are covered under their proposed PDC. For the applications that follow the risk-informed and performance-based (RIPB) approach in Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," (ADAMS Accession No. ML19241A366) (called the LMP process), the design-specific criteria identified by the RIPB approach may be used to supplement or modify the applicable GDC or Advanced Reactor Design Criteria in RG 1.232 in the formulation of PDC. It should be noted that the LMP process in NEI 18-04 is focused on off-normal conditions such as Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Beyond Design Basis Events (BDBEs) and Design Basis Accidents (DBAs) and not normal operations. Therefore, applicants using the LMP process to develop their proposed PDC will need to supplement their proposed LMP-based PDC with appropriate PDC that address safety functions and/or regulatory compliance associated with normal operations. If a prospective applicant submits a topical report proposing PDC for its design, the NRC staff will review its proposed PDC to determine if they are acceptable. In a PDC topical report, LWR applicants should discuss how the GDC will be applied to their designs and discuss any proposed exemptions to the GDC.

- **Selection of licensing basis events and classification and treatment of structures, systems, and components**

  a) The prospective applicant should submit its proposed process for selection of licensing basis events and classification and treatment of SSCs, or indicate that it plans to use an approved process such as the process described in NEI 18-04 and RG 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (ADAMS Accession No. ML20091L698).

  b) The prospective applicant should submit the anticipated list of licensing basis events and the associated list of safety-related and risk-significant SSCs to improve understanding of the design, to support discussions on the preliminary SSC classifications, and to prepare for an efficient and effective application review.

- **Fuel qualification and testing**

  Preapplication engagement on fuel design, including fuel qualification, should include the following steps: staff consideration of the fuel qualification plan and associated methodologies, potential staff observation of execution of the testing, and verification of the results of the testing to support qualification of the fuel for the associated reactor design. Prospective applicants will ultimately need to demonstrate that the fuel is qualified for use in their reactor designs (i.e., demonstrate that fuel manufactured in accordance with a specification will perform as described in the safety analysis). A TR on fuel design and qualification should include information sufficient to conclude that:

- The role of fuel performance in the safety analysis is adequately described. This can be addressed by describing how the fuel will be designed to perform during (1) normal operation, including the effects of anticipated operational occurrences, and (2) accident conditions. Sufficient information should be provided to describe the design limits for the fuel and the fuel contribution in the accident source term. Understanding of the design limits and source term should address uncertainty associated with any limitations on data available during the pre-application stage.

- The fuel qualification plan is adequate. Information should be provided in the fuel qualification plan that describes proposed analysis methodologies (e.g., fuel performance codes), the use of existing data, and any ongoing testing or plans to utilize lead test specimens. Where legacy data is used, a justification should be provided for the applicability of the data to the current application (e.g., data was collected for a fuel fabricated consistent with the proposed fuel design and irradiated in an applicable environment). In addition, justification that the data was collected under an adequate quality assurance program commensurate with the safety significance and in conformance with NRC quality assurance requirements should be provided.

- **Mechanistic or accident source term development**[8]

  A prospective applicant may submit its source term methodology to the NRC staff in a TR for review during preapplication. The source term methodology needs to include radiological source terms for effluents, radwaste system design, shielding design, and equipment qualification and should include validation and verification of associated engineering computer programs.

- **Quality assurance program**

  Prospective applicants may submit a TR that includes a quality assurance program description (QAPD) for NRC review during the pre-application phase to ensure that the design and the application will be developed in accordance with 10 CFR Part 50, Appendix B. The QAPD should cover the scope of the planned type of license application (e.g., 10 CFR 52.47(a)(19) discusses the quality assurance program (QAP) requirements for DC applications and 10 CFR 52.79(a)(25) discusses the QAP requirements for COL applications) as applied to the fabrication, construction, and testing of the SSCs of the facility. The QAPD should include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 have been and will be satisfied, including a discussion of how the QAP will be implemented.

- **Safety and accident analysis methodologies and associated validation**

  Prospective applicants should develop and execute plans to perform safety and accident analyses that include testing of safety features to support validation and verification of associated engineering computer programs. Any TRs requesting approval of these analysis plans need to include development of associated methodologies and applications of those methods, which include but are not limited to event-specific analysis methodologies, scaling methodology, setpoint

[8] Developers of light-water small modular reactors may use the accident source term in NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," or propose a design-specific accident source term.

methodology, reactor coolant analysis methodology, core design methodology, and reactivity control methods. The analysis plans need to include a test plan and test program to ensure appropriate verification and validation of the engineering computer programs, including consideration of appropriate quality assurance requirements. The test program should satisfy 10 CFR 50.43(e), which requires applicants to demonstrate that sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions.

B. Safety review meetings, audits, and white papers:

In addition to the topical reports discussed above, applicants should engage in pre-application interactions on the key topics below. The NRC staff will consider the information submitted or discussed and will provide feedback to the applicant which will be useful in preparation of the application.

- **Probabilistic risk assessment (PRA)**

The PRA provides important insights in the selection of licensing basis events, safety classification of SSCs and associated risk-informed special treatments, and determination of defense-in-depth (DID) adequacy. As such, early regulatory engagement on the PRA can make the review of an application more effective and efficient.

The applicant should facilitate the NRC staff's audit of the PRA peer review during the pre-application phase. The applicant should explain how the PRA will be used to support its application (e.g., risk-informed licensing, licensing basis event selection, siting, emergency preparedness, use of maintenance rule, etc.) to determine acceptability of the PRA for its planned use. The applicant should describe the development of its PRA, highlighting the use of any approaches that differ significantly from endorsed consensus codes and standards and NRC staff-approved guidance. The NRC staff will audit the resolution of the peer review findings and observations if a peer review has been completed. The NRC staff will provide feedback on these topics during the pre-application interactions. The applicant should address any issues identified before submittal of the application.

Pre-application interactions on the PRA and its results should also assist the NRC staff in gaining valuable risk insights on the plant design. These risk insights will help the NRC staff conduct the application review by enabling the use of such risk insights in determining the depth and scope of the review, as well as by facilitating the use of risk-informed decision-making.

For applications submitted under 10 CFR Part 50, the degree of realism and the level of detail represented in the PRA at the CP stage will be less than that available at the operating license stage. For applications submitted under 10 CFR Part 52, the PRA at the design certification stage may incorporate certain bounding analyses that will be compared to site-specific information at the COL stage. The NRC staff will adjust the depth and scope of its review, including consideration of the PRA acceptability appropriate to the maturity of the design and the type of license, permit, or certification under consideration. If an applicant considers seeking approval of design features at the CP stage, such as risk-informed licensing basis event selection or SSC classification, the PRA would need to be at a state of development that would support NRC staff's decisions in these areas. Early pre-application discussion with the NRC staff is important in this area to receive timely feedback.

- **Analysis of applicable regulations**

The applicant should submit an analysis listing those 10 CFR Part 50 or Part 52 requirements for which the applicant plans to request an exemption or for which the Commission could issue a case-specific order or rule of particular applicability.[9] This would allow the NRC staff and the applicant to establish an efficient approach for reviewing proposed exemption requests or developing a case-specific order or rule of particular applicability for the Commission's consideration. Case-specific orders have been used to license new facilities and technologies (e.g., Louisiana Energy Services, L.P., enrichment facility application). Examples of potential exemption requests may include emergency planning zone size and number of armed responders for physical security in advance of completion of ongoing rulemakings. This analysis should be informed by the information found in Appendix B of this document, "Analysis of Applicability of NRC Regulations to Non-Light-Water Power Reactors."

- **Policy issues**

The wide range of designs and design features being contemplated by advanced reactor designers may present unique regulatory issues. The NRC staff will consider these issues, as presented in white papers or at meetings, as early as possible so that they can be properly addressed before the application is submitted. Early engagement will allow time to pursue a Commission decision for policy matters warranting Commission attention. If additional policy issues arise during the application review, the schedule may be affected.

[9] In lieu of exemptions, applicants may petition for a rule of particular applicability, or the Commission can issue a case-specific order to govern specific matters. These are discussed further in Enclosure 2 to SECY 20-0093, Policy and Licensing Considerations Related to Micro-Reactors (ADAMS Accession No. ML20254A366).

- **Novel design features or approaches**

A prospective applicant should identify any novel design features through white papers or meetings during the pre-application review to allow staff familiarization so staff can develop a review strategy and review guidance, if needed. If the prospective applicant intends to use novel design features (such as passive systems, inherent safety features, or simplified control features), early identification of these features or approaches to the NRC staff will facilitate timely identification and resolution of any unique regulatory topics. Topics to be considered beyond the reactor system include unique features such as seismic isolators, novel digital instrumentation and control systems, physical and cyber security features, safeguards features, or novel approaches to operational programs. Under 10 CFR 50.43(e), the performance of each safety feature must be demonstrated, and it must be demonstrated that the interdependent effects among the safety features of the design is acceptable. The applicant should inform the NRC how this demonstration will be made in its application.

- **Consensus codes and standards and code cases**

During pre-application interactions, a prospective applicant should use a white paper to identify any consensus codes and standards or code cases it intends to use and specifically identify any standards or code cases that have not been endorsed or previously accepted by the staff. For any such standards or code cases, the prospective applicant should engage in pre-application discussions to identify any areas where additional information may be needed in the application to support the proposed approach.

- **Material Qualification**

There is a significant lead time for materials testing. As such, a prospective applicant should engage with the NRC staff on materials qualification and the development of qualification plans, when necessary, for all materials used in safety-related or risk-significant applications. The methods of engagement, level of detail, maturity of testing programs, and, if needed, approval of qualification plans via topical report review, will vary depending on several factors, including the proposed application type (e.g., CP, COL, DC).

Robust material qualification plans generally have the following attributes:

1. The plan demonstrates how data is collected in accordance with the applicable endorsed ASME BPV Code (the Code), including any endorsement conditions

2. The plan addresses how appropriate environmental testing (i.e., coolant, environment, irradiation) was performed

3. Data encompasses operating and accident conditions, and

4. Data is provided to justify the use of non-Code qualified materials.

C. Environmental activities

The NRC conducts its environmental review in accordance with the National Environmental Policy Act's requirement that Federal agencies assess the environmental effects of proposed actions significantly affecting the quality of the human environment prior to making decisions. The environmental review is an integral but distinct part of the NRC's licensing review.

Early and frequent pre-application interaction is a key component of federal directives outlined in Title 41 of the Fixing America's Surface Transportation Act (FAST-41) to streamline the NRC's environmental review process. As part of these pre-application interactions, the NRC staff encourages prospective applicants to conduct meetings, support audits, and provide white papers beginning approximately 2 years in advance of the application submittal. A prospective applicant seeking greater confidence in a predictable review schedule should engage in substantive pre-application interactions with the NRC staff as early as possible in the planning process in accordance with 10 CFR 51.40, "Consultation with NRC staff," and as discussed in RG 1.206, "Applications for Nuclear Power Plants" (ADAMS Accession No. ML18131A181). In addition, a prospective applicant should describe how it plans to address the environmental issues described in RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," (ADAMS Accession No. ML18071A400). (RG 4.2 provides guidance to applicants for the format and content of environmental reports (ERs) that are submitted as part of an application for a permit, license, or other authorization to site, construct, and/or operate a new nuclear power plant.) A prospective applicant should also provide a justification for its plans to omit analysis of any issue it believes need not be analyzed in the ER. In addition, a prospective applicant should also consider following the below guidance in preparing an ER:

- COL/ESP-ISG-026, "Interim Staff Guidance on Environmental Issues Associated with New Reactors," (ADAMS Accession No. ML13347A915)

- COL/ESP-ISG-027, "Interim Staff Guidance on Specific Environmental Guidance for Light Water Small Modular Reactor," (ADAMS Accession No. ML14100A153)

- Interim Staff Guidance (ISG)-29, "Environmental Considerations Associated with Micro-reactors," (ADAMS Accession No. ML20252A076).

Further, industry developed NEI 10-07, Revision 1, "Industry Guideline for Effective Pre-Application Interactions with Agencies Other Than NRC During the Early Site Permit Process (ADAMS Accession No. ML13028A392) that is endorsed in RG 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," (ADAMS Accession No. ML18071A400).

Early engagement is important for assuring that sufficient data is available in the application and that appropriate engagement with other Federal and State agencies has begun. For example, a project may affect a threatened or endangered species, necessitating consultation with the U.S. Fish and Wildlife Service. If the service or the NRC need data on the species, seasonal lifecycles could affect the ability to collect the data, which in turn could delay a project.

White Papers

A prospective applicant should submit white papers on the following key areas and on any novel approaches to environmental topics. The NRC staff will consider the approaches, document a position, and provide feedback to the applicant during the pre-application phase, as requested and appropriate.

1. **Unique or Novel Methodologies and Issues**

   The prospective applicant should identify any novel environmental methodology or issue to allow staff familiarization so it can develop a review strategy and review guidance, if needed. An example of a unique issue would be a purpose and need statement for the project that specifies uses other than electricity production. The purpose and need for the project is the foundation on which the environmental review is based. The purpose and need statement informs analyses of the need for the project and of alternatives, including alternative sites and alternative sources of energy.

2. **Alternatives to the Proposed Project**

   A recurring issue on many of the previous COLs and ESPs was the alternative site selection process. The prospective applicant should support meetings to discuss the site selection process with the NRC staff. In addition, energy alternatives could be a unique issue for an advanced reactor application, depending on the purpose and need statement for the project. A purpose other than generating baseload electricity could change the alternative energy analysis, relative to what was previously considered for large LWRs.

3. **Cooling Water Availability**

   The NRC staff understands that an advanced reactor may use less cooling water than a large LWR in the operating reactor fleet; however, applicants need to obtain access to any necessary cooling water from the relevant permitting authorities. The NRC staff will analyze the alternatives and the environmental effects of the proposed use of cooling water in the EIS. Therefore, the staff encourages a prospective applicant to provide information during pre-application interactions on the proposed facility's water consumption so the staff can gain an understanding of the facility's water needs and assess the appropriateness of the permits being sought. The staff also recommends that the prospective applicant, the NRC staff, and the water permitting agencies meet at least once during the pre-application activities.

4. **Status of Permits and Authorizations for the Proposed Project**

   Prospective applicants should interact with other permitting agencies as discussed in NEI 10-07, "Industry Guideline for Effective Pre- Application Interactions with Agencies Other Than NRC During the Early Site Permit Process," and provide to the NRC staff a list of the needed authorizations, permits, licenses, and approvals for the project. This documentation should also contain a timeline for obtaining the necessary permits and the current status. The prospective applicant should also provide copies of available correspondence between the applicant and State Historic Preservation Office (SHPO), Tribes, U.S. Fish and Wildlife Service, U.S. Army Corps of Engineers, National Marine Fisheries Service (NMFS), and state and local officials. A prospective applicant may need to provide information describing any required consistency determination under the Coastal Zone Management Act. The NRC staff will review the information and identify any additional information the NRC will need to complete its EIS.

Meetings

The following topics are critical components of environmental reviews and warrant close attention. Inadequate research and analysis of any one of these issues has the potential to extend the schedule for EIS preparation. Both the prospective applicant and the NRC staff would benefit from early discussion of any special aspects of these topics and a description of the applicant activities in these areas.

- Socioeconomic characteristics of the community.
- Aquatic or terrestrial ecology studies that have been performed (if any).
- Federally listed species and critical habitats present, and potential impacts on those species and habitats
- Potential impacts on Essential Fish Habitat, including prey of Federally managed species.
- Historic properties and other cultural resources within the direct and indirect areas of potential effect (APE). Summarize cultural resource investigations conducted in the APE (all past and current historic and cultural resource investigations), and outreach conducted with the SHPO, Tribal Historic Preservation Officer, American Indian Tribes, and interested parties.
- The fuel cycle and its impacts as related to the reactor design including the management of spent nuclear fuel.
- The environmental impacts from the transportation of fuels and wastes.
- Design-specific information needed for the environmental review including:
    - Radiological health impacts (10 CFR Part 20 exposure analysis, annual population dose, non-human biota dose),
    - Radiological waste management including effluent releases and solid wastes, as applicable,
    - Non-radiological waste management, and
    - Postulated accidents and severe accident mitigation design alternatives, as applicable.

D. Pre-application Readiness Assessment

In addition to the above pre-application activities, the prospective applicant should allow the staff to conduct a pre-application readiness assessment (see Office instruction LIC-116, "Pre-application Readiness Assessment," ADAMS Accession No. ML20104B698) of both safety and environmental topics. In accordance with the Office Instruction, the readiness assessment may focus on either the whole application or selected parts identified in early interactions between the staff and prospective applicant. Depending upon the type of application to be submitted and the extent of pre-application activities leading up to this point, the staff will propose a right-sized scope for the readiness assessment.

The readiness assessment would allow the NRC staff to: (1) identify information gaps between the draft application and the technical content needed in the application submitted to the NRC, (2) identify major technical and/or policy issues not previously identified that may adversely impact the docketing or technical review of the application, and (3) become familiar with the application, particularly in areas where prospective applicants are proposing new concepts or novel design features not previously identified. The results of the readiness assessment will inform prospective applicants in completing their applications and assist the NRC staff in planning its resources for the review once the application is formally submitted. The staff plans to engage prospective applicants to schedule a pre-application readiness assessment at least 6 months prior to the anticipated date of submittal. The readiness assessment is not part of the NRC's official acceptance review process and does not predetermine whether the application will be docketed. A prospective applicant should provide the most current draft of the safety analysis report and environmental report, referenced documentation, and prospective applicant staff and contractors to assist the NRC staff during its readiness assessment.

E. Safeguards Information Plan

NRC staff review of an applicant's plan for the protection of safeguards information (SGI) during the pre-application period will enable the staff to provide the applicant with SGI information, as necessary, for the applicant to consider safeguards and security in the design of the facility. In addition, this will enable the applicant to develop the physical security program in accordance with the requirements of 10 CFR Part 73, "Physical Protection of Plants and Materials," and 10 CFR 50.150, "Aircraft impact assessment."

APPENDIX B - Analysis of Applicability of NRC Regulations to Non-Light-Water Power Reactors

Purpose

This Appendix identifies regulations that are generically applicable and inapplicable to non-light-water reactor (non-LWR) applications for construction permits and operating licenses for power reactors under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 and standard design certifications, combined licenses, and standard design approvals under 10 CFR Part 52.[1] "Applicable regulations," in the context of this Appendix, are Nuclear Regulatory Commission (NRC) regulations currently in effect from which non-LWR designs are not generically excluded by the terms of the regulations. "Inapplicable regulations" are NRC regulations currently in effect from which non-LWR designs are generically excluded by the terms of the regulations.

This document is based on the NRC's current regulatory framework. Generic changes to the NRC's regulatory framework for non-LWRs, if needed, are addressed through the rulemaking process. The NRC is undertaking several rulemakings that will provide additional, performance-based options for future non-LWR applicants. One effort is the Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31), which is commonly referred to as the 10 CFR Part 53 rulemaking. Other rulemaking efforts address emergency planning and physical security.

While the rulemakings are pending, specific exemptions can provide the regulatory flexibility that a non-LWR applicant may seek. This approach is consistent with the flexibility provided for any applicant that identifies regulations that are not needed for the applicant's design or site. There are additional procedural alternatives to exemptions that the NRC has used successfully in the past to license new technologies. An applicant may request that the staff develop a rule of particular applicability or the Commission could develop an order (for example, as part of the Commission's notice of docketing and opportunity to request a hearing on the application). Such a rule or order could identify requirements particular to a design in lieu of or in addition to proposed exemptions from the applicable requirements.

Orders and rules of particular applicability are case-specific, do not apply generically to all non-LWRs, and would require resources and substantial preapplication engagement. During preapplication engagement, the NRC staff and applicant would work together to identify areas where such an order or rule would be useful to clarify the relationship between current regulatory requirements and a specific design and reduce or obviate the need for exemptions. These options are available for use in connection with a specific application, especially in cases where an applicant has a mature design and desires early Commission engagement. Preapplication engagement should help to determine if these options would be useful in a particular context. If these interactions result in a staff determination that an application-specific order (or similar action) might be useful, the staff would interact with the Commission to develop such an approach. For simplicity, the remainder of this Appendix discusses specific exemptions to address applicable regulations that are not needed for the applicant's design or site, but a prospective applicant applying for a design certification, license, or permit under 10 CFR Parts 50 and 52 could use the same analytical approach to develop the basis for the acceptability of its design and requests for exemptions from regulations as guidance to identify factors that could be addressed in a design- or facility-specific order or rule.

[1] This appendix does not include regulations associated with early site permits, limited work authorizations, and manufacturing licenses.

This document considers both 10 CFR Parts 50 and 52, which set forth different possible licensing pathways. In performing the regulatory review documented in this Appendix, the NRC staff primarily addressed 10 CFR Part 50, as it contains the full set of regulations applicable to power reactor applications and is referenced in 10 CFR Part 52 directly in many instances. Separately, the NRC staff reviewed 10 CFR Part 52 as certain regulatory requirements differ between 10 CFR Part 50 and 10 CFR Part 52. Some of these differences are due to NRC's expectation that most new reactor applicants would use 10 CFR Part 52, rather than 10 CFR Part 50, to construct and operate new reactor facilities. The NRC anticipates that a currently ongoing rulemaking (RIN 3150-AI66) will clarify Parts 50 and 52 and their interrelationship and ensure consistency in new reactor licensing reviews as well as address other new reactor licensing issues.

The goal of this Appendix is to provide guidance about which current regulatory requirements apply to non-LWR applications, but omission of any given regulation from the analysis should not be interpreted as an indication that the omitted regulation does not apply to a non-LWR applicant. For example, while not included in the tables that follow, 10 CFR 52.6, "Completeness and accuracy of information," applies to all applicants for licenses under 10 CFR Part 52, including non-LWR applicants. This Appendix is intended to provide guidance and structure regarding the regulations an applicant should address, and the staff will review how an applicant addresses these regulations once a design is mature and an application is received.

Considerations

The NRC anticipates that specific non-LWR designs may comply with applicable regulations in new and unforeseen ways. An exemption would not be required if an applicant can justify that a requirement is met for a specific design. The NRC remains receptive to discussing and considering innovative methods for demonstrating compliance with regulatory requirements. The attachment to this Appendix includes examples of demonstrating compliance with regulations that may be generically applicable to non-LWR applicants.

The NRC staff acknowledges that some of the regulations identified as generically applicable in the subsequent tables may not serve a purpose for certain non-LWR designs due to their unique design-specific attributes. The NRC staff therefore anticipates that non-LWR applicants will request exemptions from some of these regulations. In order to address the appropriate regulatory requirements, as part of the application, staff anticipates that applicants will provide information related to the overall safety of the design that serves to satisfy multiple requirements and systematically explain the facility design. In doing so, this information could provide some or all of the basis for exemptions from regulations, and thus an exemption request could be a natural extension of the application. Exemption requests ideally should be in their own section of the application, although the exemption requests need not repeat technical information presented elsewhere in the application (the exemption request can reference the relevant portion of the application). Exemption requests using the same technical justification can be bundled together into a single request at the applicant's discretion.

Applicants will be required to submit on the docket the information needed to support staff's determinations on the acceptability of each exemption request. In reviewing an exemption request under §§ 50.12 and 52.7, [2] the NRC must determine whether the requested exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. In addition, the requested exemption must provide at least one special circumstance identified in 10 CFR 50.12(a)(2). Other criteria apply for certain exemptions in 10 CFR Part 52 (see, e.g., §§ 52.93 and 52.63). The Commission ultimately determines the acceptability of the exemption request in approving or denying the issuance of the design certification rule, permit, or license.

Exemption requests will vary both in content and complexity, and the amount of supporting information needed to justify the technical and regulatory criteria associated with a specific exemption request will vary accordingly. The NRC staff expects some exemption requests to be straightforward, with minimal information needed to meet the information requirements associated with the regulation. Other exemption requests involving extensive technical justification are likely to have more complex information requirements. As long as the administrative record demonstrates that the regulatory requirements are met and the exemption request is justified, the format and content of the exemption request may differ and remain acceptable.

In general, to support an exemption request, the application should contain the following:

- A statement identifying the need for the exemption;

- The scope and summary of the requested exemption, including identification of the specific portion(s) of the regulation from which the exemption is requested;

- Relevant justification for the exemption request, with references to regulatory guidance and/or requirements (as applicable);

- A technical justification for the request (which may include references to information in other portions of the application); and

- An evaluation against the exemption criteria in §§ 50.12 and 52.7 or other specific criteria provided in 10 CFR Part 52.

There are a few special cases where something other than an exemption request may be appropriate. First, some applicable regulations such as definition sections or lists of codes and standards do not impose requirements unless they are referenced in other applicable regulations. The Attachment to this Appendix provides examples of regulations where no actions are required for regulatory compliance. Second, some regulations may be inapplicable to a particular non-LWR design or application because of entry conditions that are already present in the rule. In these cases, an applicant is expected to document and support its claim that a requirement is inapplicable because of the entry condition. Finally, some exemption requests are straightforward enough that providing a basis for them requires little information beyond the description of the design in the final safety analysis report (FSAR) as technical justification. The Attachment to this Appendix discusses regulations of this type.

[2] Applicants may request exemptions under other parts of the NRC's regulations by following the specific requirements and processes for obtaining an exemption in those parts, which may differ from those in §§ 50.12 and 52.7.

Examples of information that could be furnished to support a specific exemption request are provided in the attachment to this appendix. Prospective applicants should engage early with the NRC staff to determine the need for exemptions from specific requirements for a particular design or technology. The NRC staff will review applications to ensure that any particular non-LWR design achieves the underlying safety purpose of existing regulations, if needed to support the NRC's findings of reasonable assurance of adequate protection of public health and safety or the common defense and security to support issuance of a license.

Guidance document NEI 18-04, Revision 1, "Risk-Informed Performance-Based Guidance for Non-Light Water Reactor Licensing Basis Development," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19241A336) often referred to as the Licensing Modernization Project (LMP), describes a methodology to identify licensing basis events; categorize and establish performance criteria for structures, systems, and components (SSCs); and evaluate defense-in-depth adequacy for advanced reactor designs. The NRC staff endorsed the LMP in Regulatory Guide 1.233, "Guidance for a Technology Inclusive, Risk-informed, and Performance-based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors" (ADAMS Accession No. ML20091L698). Use of the LMP could prompt an applicant to request exemptions from certain regulations, such as the 10 CFR 50.2 definition of "safety-related structures, systems and components." The attachment to this appendix includes more information on this topic.

Analysis

The NRC staff's analysis is documented in the following tables. Additional details are provided immediately preceding each table. Table 1 provides a list of 10 CFR Part 50 regulations to be considered by non-LWR applicants, Table 2 provides a list of 10 CFR Part 52 regulations to be considered by non-LWR applicants, and Table 3 provides a list of regulations by Part outside of 10 CFR Part 50 and Part 52 that may apply to non-LWRs.

Table 4 provides a list of 10 CFR 50.34(f) (i.e., Three Mile Island (TMI)) requirements that may be technically relevant to non-LWRs. Some regulations in Table 4 include "entry conditions" that if met for a given design would make a regulation technically relevant; if the "entry conditions" are not met then the regulations are considered not technically relevant.

Table 5 provides regulations and additional context for some areas where exemptions may be appropriate for non-LWR designs. These regulations apply to all reactor designs in regard to their performance standards but include detailed descriptions of conditions found in LWRs that may not be found in certain non-LWRs or detailed compliance methods that apply to LWRs but not all non-LWRs.

Table 6 identifies 10 CFR Parts 50 and 52 regulations for which an exemption is expected for non-LWRs because the regulations apply by their terms, but cross-reference 10 CFR Part 50 regulations that are applicable to LWRs only. Where an application contains sufficient design information for the NRC staff to determine regulatory applicability and an otherwise acceptable exemption has not been formally requested, in accordance with 10 CFR 50.12(a) the Commission upon its own initiative may proactively evaluate and document the bases for exemptions to the regulations as described in Table 6 based on design information already required by NRC regulations to be included in the application. When included in an application, such information should form sufficient bases for these exemptions. The staff may request that the applicant provide additional information on the docket, where necessary, to support exemptions that the staff may consider upon its own initiative.

Regulatory Applicability for non-LWRs

In Tables 1 through 3, the applicability of a regulation to a non-LWR is indicated by either "Yes" or "No." In using the indicated applicability, the NRC staff has generated a flow chart to assist in determining how to address regulations based on the provided context. Regulations marked as "Yes" in the last column of Tables 1 through 3 are generically applicable to non-LWRs, and the flow chart in Figure 1 provides various pathways for addressing those regulations based on application-specific considerations. Further detail for some of these pathways is provided in the Attachment to this Appendix. Regulations marked as "No" in the last column of Tables 1 and 2 are generically not applicable to any non-LWR and the application need not include further information to address such a regulation.

Figure 1. Using Regulatory Applicability Tables (Flow Chart)

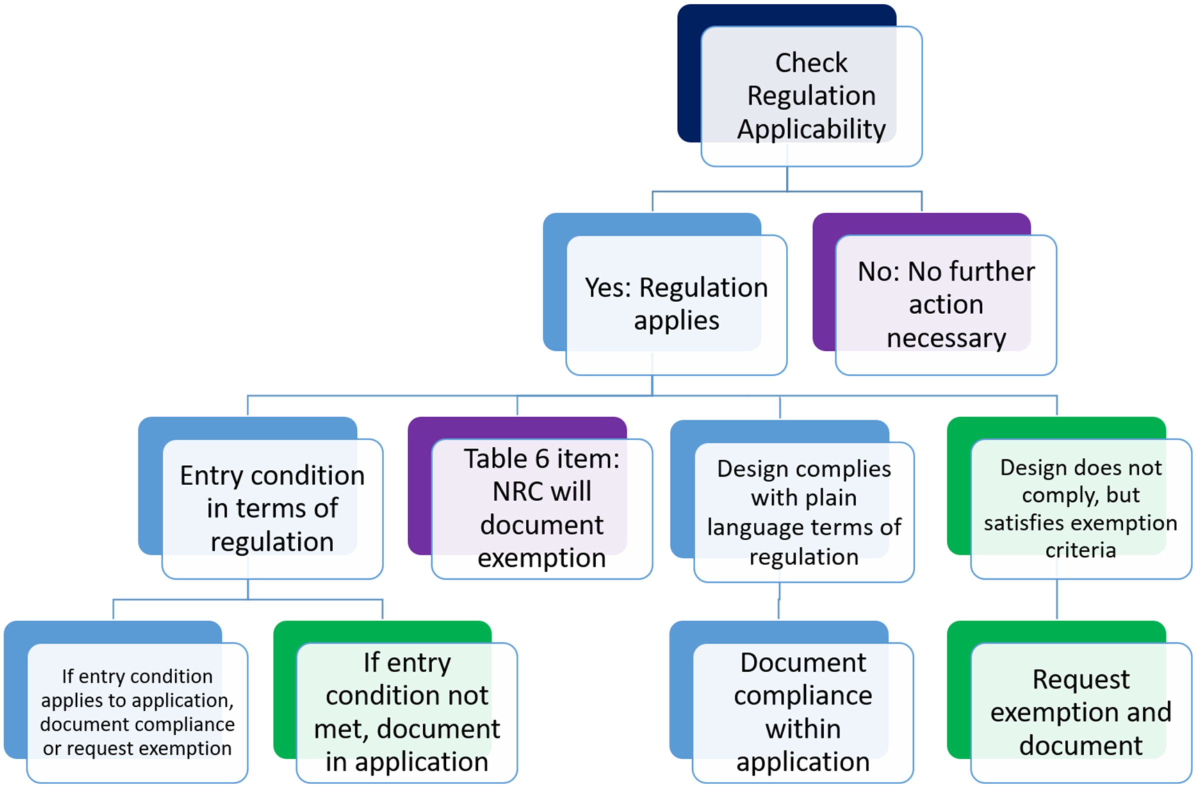

Table 1

Table 1 provides a list of 10 CFR Part 50 regulations to be considered by non-LWR applicants, with applicability for each regulation in the table. It lists regulations by 10 CFR citation, provides a brief description of the regulation, and lists applicability (with notes for some regulations).

Table 1. 10 CFR Part 50 Requirements, as applicable to applications under Part 50 for non-LWRs[3]

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.2	Definitions	Yes
§ 50.3	Interpretations	Yes
§ 50.4	Written communications	Yes
§ 50.5	Deliberate misconduct	Yes
§ 50.7	Employee protection	Yes

[3] Omission of any given regulation from the tables should not be interpreted as a non-applicability.

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.9	Completeness and accuracy of information	Yes
§ 50.10	License required; Limited work authorization (LWA)	Yes
§ 50.11	Exceptions and exemptions from licensing requirements	Yes
§ 50.12	Specific exemptions	Yes
§ 50.13	Attacks and destructive acts by enemies of the United States; and defense activities	Yes
§ 50.20	License classification	Yes
§ 50.21	Class 104 licenses for commercial and industrial facilities	Yes
§ 50.22	Class 103 licenses for commercial and industrial facilities	Yes
§ 50.23	Construction permits (CPs)	Yes (for CPs)
§ 50.30	Filing of application; oath or affirmation	Yes
§ 50.31	Combining applications	Yes
§ 50.32	Elimination of repetition	Yes
§ 50.33	Content of applications; general information	Yes
§ 50.34(a)	Preliminary safety analysis report (PSAR)	Yes (for CPs)
§ 50.34(b)	FSAR	Yes (for OLs)
§ 50.34(b)(1)	Site Evaluation (10 CFR Part 100) for Operating License Applications	Yes
§ 50.34(b)(2)	FSAR description of SSCs	Yes

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.34(b)(3)	Kinds and quantities of radioactive materials (10 CFR Part 20)	Yes
§ 50.34(b)(4)	Analysis of SSCs and Emergency Core Cooling System (ECCS) evaluation	See Analysis of SSCs and ECCS Evaluation in Table 5
§ 50.34(b)(5)	Description and evaluation of applicable programs including research and development	Yes
§ 50.34(b)(6)	Facility operation documentation (programs, TS, etc.)	Yes
§ 50.34(b)(7)	Technical qualifications	Yes
§ 50.34(b)(8)	Operator requalification program	Yes
§ 50.34(b)(9)	Description of pressurized thermal shock	See Pressurized Thermal Shock Events in Table 5
§ 50.34(b)(10)	Earthquake engineering criteria in Appendix S of 10 CFR Part 50	Yes[4]
§ 50.34(b)(11)	Siting criteria	Yes
§ 50.34(b)(12)	Aircraft impact	Yes
§ 50.34(c)	Physical security plan	Yes (for OLs)
§ 50.34(d)	Safeguards contingency plan	Yes (for OLs)
§ 50.34(e)	Protection against unauthorized disclosure	Yes (for OLs)
§ 50.34(f)	TMI-related requirements	No[5]

[4] Although GDC 2 of 10 CFR Part 50, Appendix A, is not directly applicable to non-LWRs as a minimum standard for the development of principal design criteria (PDCs) required by § 50.34(a)(3), it provides guidance for their development. This requirement and that of § 50.34(a)(12) implement the requirements of 10 CFR Part 50, Appendix S, "Earthquake Engineering Criteria for Nuclear Power Plants," in partial conformance to the PDC corresponding to GDC 2 and should be followed unless the NRC staff reviews and approves PDC for the facility that do not include an earthquake hazard.

[5] Although not required for applications under 10 CFR Part 50, the Commission direction in the Staff Requirements Memorandum to SECY-15-0002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," September 22, 2015 (ADAMS Accession No. ML15266A023), confirmed that its earlier

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.34(g)	Combustible gas control	Yes
§ 50.34(h)	Conformance with the Standard Review Plan (SRP)	No
§ 50.34(i)	Mitigation of beyond-design-basis events	Yes (for OLs)
§ 50.34a	Design objectives for equipment to control releases of radioactive material in effluents	Yes
§ 50.36	Technical specifications	Yes
§ 50.36a	Technical specifications on effluents from nuclear power reactors	Yes
§ 50.43(e)(1)	Additional standards and provisions affecting Class 103 licenses and certifications for commercial power	Yes
§ 50.43(e)(2)	Additional standards and provisions affecting Class 103 licenses and certifications for commercial power	Yes
§ 50.44(a)	Combustible gas control for nuclear power reactors	Yes
§ 50.44(b)	Combustible gas control for nuclear power reactors	No
§ 50.44(c)	Combustible gas control for nuclear power reactors	No
§ 50.44(d)	Combustible gas control for nuclear power reactors	Yes

directions for the 10 CFR Part 52 new power reactor applications be applied consistently to 10 CFR Part 50 new power reactor applications. In addition, the Commission approved commencing a rulemaking to revise the regulations in 10 CFR Part 50 for new power reactor applications to more closely align with requirements in 10 CFR Part 52, incorporating the requirements identified by the staff in SECY-15-0002, Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," (ADAMS Accession No. ML13277A420), including the technically relevant TMI-related items under 10 CFR 50.34(f) and the PRA requirements under section 50.71(h). Staff should ensure that an applicant addresses the technically relevant TMI-related items during the review process and propose license conditions requiring the appropriate items in the interim.

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.45	Standards for construction permits, operating licenses, and combined licenses	Yes
§ 50.46	Acceptance criteria for emergency core cooling systems	No
§ 50.46a	Acceptance criteria for reactor coolant system venting systems	Yes, but only required (per the text in the regulation) for a design where the accumulation of noncondensible gases would cause the loss of function of the core cooling systems
§ 50.46a(a)	Acceptance criteria for reactor coolant system venting systems	See Analysis of SSCs and ECCS Evaluation in Table 4
§ 50.46a(b)	Acceptance criteria for reactor coolant system venting systems	See Analysis of SSCs and ECCS Evaluation in Table 4
§ 50.46a(c)	Acceptance criteria for reactor coolant system venting systems	See Analysis of SSCs and ECCS Evaluation in Table 4
§ 50.47	Emergency plans	Yes (for OLs)
§ 50.48(a)	Fire protection plan	Yes
§ 50.48(b)	Fire protection (Appendix R)	No, § 50.48(b) only applies to certain nuclear power plants licensed to operate before January 1, 1979.
§ 50.48(c)	National Fire Protection Association Standard (NFPA) 805	No, § 50.48(c) provides an alternate approach for plants licensed to operate before January 1, 1979, to comply with § 50.48(b) or their fire protection license conditions.
§ 50.49	Environmental qualification of electric equipment important to safety for nuclear power plants	Yes, except as noted below
§ 50.49(g)	Environmental qualification of electric equipment important to safety for nuclear power plants	No

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.49(h)	Environmental qualification of electric equipment important to safety for nuclear power plants	No
§ 50.49(i)	Environmental qualification of electric equipment important to safety for nuclear power plants	No
§ 50.49(k)	Environmental qualification of electric equipment important to safety for nuclear power plants	No
§ 50.50	Issuance of licenses and construction permits	Yes
§ 50.51	Continuation of license	Yes
§ 50.52	Combining licenses	Yes
§ 50.53	Jurisdictional limitations	Yes
§ 50.54	Conditions of licenses	Yes, (for operating licenses/combined licenses (OLs/ COLs) as described in the text of the regulation)
§ 50.54(a)	Quality assurance	Yes
§ 50.54(j)	Reactivity manipulation	Yes
§ 50.54(k)	Operator at the controls	Yes
§ 50.54(m)	Staffing requirements	Yes
§ 50.54(o)	Primary containment/Appendix J applicability	No
§ 50.54(ff)	Seismic	Yes[6]

[6] Although GDC 2 of 10 CFR Part 50, Appendix A, is not directly applicable to non-LWRs as a minimum standard for the development of PDCs required by § 50.34(a)(3), it provides guidance for their development. Sections 50.34(a)(12) and 50.34(b)(10) implement the requirements of 10 CFR Part 50, Appendix S, “Earthquake Engineering Criteria for Nuclear Power Plants,” in partial conformance to the PDC corresponding to GDC 2 and should be followed unless the NRC staff reviews and approves PDC for the facility that do not include an earthquake hazard. Sections 52.47(a)(20), 52.79(a)(19), 52.137(a)(20), and 52.157(a)(14) implement the requirements of 10 CFR

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.54(hh)	Aircraft Threat	Yes
§ 50.55	Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses	Yes
§ 50.55a(a)	Codes and standards	Yes, the provision provides a list of standards approved for incorporation by reference but does not itself impose requirements
§ 50.55a(b)	Codes and standards - use and conditions on the use of standards	No[7]
§ 50.55a(c)	Codes and standards - reactor coolant pressure boundary	No
§ 50.55a(d)	Codes and standards - Quality Group B components	No
§ 50.55a(e)	Codes and standards - Quality Group C components	No
§ 50.55a(f)	Codes and standards – preservice and inservice testing requirements	No
§ 50.55a(g)	Codes and standards – Preservice and inservice inspection requirements	No
§ 50.55a(h)(2)	Codes and standards	No
§ 50.55a(h)(3)	Codes and standards	Yes
§ 50.55a(z)	Codes and standards	Yes
§ 50.56	Conversion of construction permit to license; or amendment of license	Yes

Appendix S without reference to GDC 2. Section 50.54(ff) implements the requirements of 10 CFR Part 50, Appendix S, paragraph IV(a)(3) for plants that have implemented Appendix S, providing criteria a licensee shutting down as a result of vibratory ground motion exceeding the Operating Basis Earthquake must meet prior to resuming operations.

[7] Note that these standards marked as "No" do not apply as requirements to non-LWRs, but some non-LWRs may elect to use these codes and standards to demonstrate quality and capability of structures, systems, or components. NRC staff should review the use of existing codes and standards that are relevant, incorporating the conditions on their use in the regulations (such as those in section 50.55a(b)) that are applicable to the design. The use of existing codes and standards, when relevant, can provide a recognized quality standard and alleviate much of the need to justify component quality on a specific basis at the design stage.

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.57	Issuance of operating license	Yes
§ 50.58	Hearings and report of the Advisory Committee on Reactor Safeguards	Yes
§ 50.59	Changes, tests, and experiments	Yes
§ 50.60	Acceptance criteria for fracture prevention measures for LWRs for normal operation	No
§ 50.61	Fracture toughness requirements for protection against pressurized thermal shock events	No
§ 50.61a	Alternate fracture toughness requirements for protection against pressurized thermal shock events	No
§ 50.62	Requirements for reduction of risk from Anticipated Transient Without Scram (ATWS) events for LWRs	No
§ 50.63	Loss of all alternating current power	No
§ 50.65	Maintenance rule	Yes, also see Reactor Coolant Pressure Boundary in Table 5 as applicable
§ 50.66	Requirements for thermal annealing of the reactor pressure vessel	No
§ 50.67	Accident source term	No
§ 50.68	Criticality accident requirements	Yes, See Criticality Monitoring in Table 5
§ 50.69	Risk-informed categorization and treatment of SSCs	Yes, voluntary (as applicable)
§ 50.70	Inspections	Yes

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.71	Maintenance of records, making of reports	Yes
§ 50.71(h)(1)	Probabilistic risk assessment (PRA)	Yes,[4] an exemption may not be required if a Level 3 PRA is done because the scope of the Level 3 PRA encompasses the Level 1 and Level 2 PRAs.
§ 50.72	Immediate notification requirements for operating nuclear power reactors	Yes (for OLs/COLs)
§ 50.73	Licensee event report system	Yes (for OLs/COLs)
§ 50.74	Notification of change in operator or senior operator status	Yes
§ 50.75	Reporting and recordkeeping for decommissioning planning	Yes
§ 50.76	Licensee's change of status; financial qualifications	Yes
§ 50.78	Facility information and verification	Yes
§ 50.80	Transfer of licenses	Yes
§ 50.81	Creditor regulations	Yes
§ 50.82	Termination of license	Yes
§ 50.83	Release of part of a power reactor facility or site for unrestricted use	Yes
§ 50.90	Application for amendment of license, construction permit, or early site permit	Yes
§ 50.91	Notice for public comment; State consultation	Yes
§ 50.92	Issuance of amendment	Yes

Table 1: Regulation	Topic	Applicable to non-LWRs
§ 50.100	Revocation, suspension, modification of licenses, permits, and approvals for cause	Yes
§ 50.101	Retaking possession of special nuclear material	Yes
§ 50.102	Commission order for operation after revocation	Yes
§ 50.103	Suspension and operation in war or national emergency	Yes
§ 50.109	Backfitting	Yes
§ 50.110	Violations	Yes
§ 50.111	Criminal penalties	Yes
§ 50.120	Training and qualification of nuclear power plant personnel	Yes (for OLs)
§ 50.150	Aircraft impact	Yes (for CPs/OLs/COLs)
§ 50.155	Mitigation of beyond-design-basis events	Yes
10 CFR Part 50 Appendix A	General Design Criteria	No[8]
10 CFR Part 50 Appendix B	Quality assurance	Yes
10 CFR Part 50 Appendix C	Financial data and qualifications	Yes
10 CFR Part 50 Appendix E	Emergency planning	Yes
10 CFR Part 50 Appendix F	Fuel reprocessing plants and related waste management facilities	Yes, for non-LWRs with reprocessing plants on site

[8] While Appendix A is not a requirement, applicants for Part 50 or Part 52 reactor licenses are required to provide principal design criteria (PDC). 10 CFR Part 50, Appendix A provides guidance for applicants for non-LWRs in establishing PDCs.

Table 1: Regulation	Topic	Applicable to non-LWRs
10 CFR Part 50 Appendix G	Fracture toughness requirements	No
10 CFR Part 50 Appendix H	Reactor vessel material surveillance program requirements	No
10 CFR Part 50 Appendix I	Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents	No
10 CFR Part 50 Appendix J	Primary reactor containment leakage testing for water-cooled power reactors	No
10 CFR Part 50 Appendix K	ECCS evaluation models	No
10 CFR Part 50 Appendix N	Standardization of nuclear power plant designs	Yes
10 CFR Part 50 Appendix Q	Preapplication early review of site suitability issues	Yes
10 CFR Part 50 Appendix R	Fire protection	No
10 CFR Part 50 Appendix S	Earthquake engineering criteria	Yes[9]

<u>Table 2</u>

Table 2 includes select regulations for 10 CFR Part 52, Subpart B, “Standard Design Certifications,” Subpart C, “Combined Licenses,” and Subpart D, “Standard Design Approvals,” because these are the types of Part 52 applications expected by the NRC staff for most non-LWRs. Similar or additional requirements exist for manufacturing licenses. Table 2 lists

[9] Although GDC 2 of 10 CFR Part 50, Appendix A, is not directly applicable to non-LWRs as a minimum standard for the development of PDCs required by § 50.34(a)(3), it provides guidance for their development. Sections 50.34(a)(12), 50.34(b)(10), 52.47(a)(20), 52.79(a)(19), 52.137(a)(20), and 52.157(a)(14) implement the requirements of 10 CFR Part 50, Appendix S, “Earthquake Engineering Criteria for Nuclear Power Plants,” in partial conformance to the PDC corresponding to GDC 2 and should be followed unless the NRC staff reviews and approves PDC for the facility that do not include an earthquake hazard.

regulations by topic, provides associated 10 CFR citations, and identifies expected applicability (with notes for some regulations).

Table 2. Selected 10 CFR Part 52 Requirements, as applicable to non-LWR Standard Design Certifications, Combined Licenses and Standard Design Approvals Applications[10]

Table 2. Topic	Regulation	Applicability to non-LWRs
Analysis of SSCs and ECCS Evaluation	§ 52.47(a)(4) § 52.79(a)(5) § 52.137(a)(4)	See Analysis of SSCs and ECCS Evaluation in Table 6
Applicability of SRP	§ 52.47(a)(9) § 52.79(a)(41) § 52 137(a)(9)	No
Combustible Gas Control	§ 52.47(a)(12) § 52.79(a)(8) § 52.137(a)(12)	Yes
Pressurized Thermal Shock	§ 52.47(a)(14) § 52.79(a)(7) § 52.137(a)(14)	See Pressurized Thermal Shock Events in Table 6
Anticipated Transient Without Scram (ATWS)	§ 52.47(a)(15) § 52.79(a)(42) § 52.137(a)(15)	See ATWS in Table 6
Station Blackout (SBO)	§ 52.47(a)(16) § 52.79(a)(9) § 52.137(a)(16)	See SBO in Table 6
Criticality Accident Requirements	§ 52.47(a)(17) § 52.79(a)(43) § 52.137(a)(17)	See Criticality Monitoring in Table 5
Fire protection	§ 52.47(a)(18) § 52.79(a)(6) § 52.137(a)(18)	Yes[11]

[10] Omission of any given regulation from the tables should not be interpreted as a non-applicability.
[11] These regulations require submittal of information on compliance with the fire protection requirements in § 50.48, which is applicable to non-LWRs, and Part 50, Appendix A, GDC 3, which is not directly applicable to non-LWRs. Because the GDCs in Part 50, Appendix A, provide the minimum standards for PDCs established by a designer for an LWR application and are not requirements for non-LWR applications but provide only guidance for non-LWR designers to use in the establishment of their PDCs, these requirements should be interpreted as addressing the PDC established by the non-LWR designer that corresponds to GDC 3 rather than to GDC 3 itself.

Table 2. Topic	Regulation	Applicability to non-LWRs
Fire Protection Program	§ 52.79(a)(40)	Yes
Unresolved Safety Issues (USI) Resolution	§ 52.47(a)(21) § 52.79(a)(20) § 52.137(a)(21)	Yes
Operating Experience	§ 52.47(a)(22) § 52.79(a)(37) § 52.137(a)(22)	Yes
Severe Accident Considerations	§ 52.47(a)(23) § 52.79(a)(38) § 52.137(a)(23)	No
Conceptual Design Information Not Part of the Certification	§ 52.47(a)(24)	Yes
Interface requirements to be met by those portions of the facility that are not part of the certification	§ 52.47(a)(25), (26)	Yes
PRA	§ 52.47(a)(27) § 52.79(a)(46) § 52.137(a)(25)	Yes
ITAAC	§ 52.47(b)(1) § 52.80(a)	Yes
Environmental report	§ 52.47(b)(2) § 52.80(b)	Yes (DC and COL only)[12]
Designs that Differ Significantly from LWRs Must Meet Section 50.43(e)	§ 52.47(c)(2) § 52.79(a)(24) § 52.137(b)	Yes
Environmental Qualification of Electrical Equipment	§ 52.47(a)(13) § 52.79(a)(10) § 52.137(a)(13)	Yes
American Society of Mechanical Engineers (ASME) Code Programs	§ 52.79(a)(11)	Yes[13]

[12] Standard design approvals are categorically excluded from the requirements for environmental reports under § 51.22(c).
[13] Note that these standards from 10 CFR 50.55a that are marked as “No” in Table 1 do not apply as requirements to non-LWRs, but some non-LWRs may elect to use these codes and standards to demonstrate quality and capability of

Table 2. Topic	Regulation	Applicability to non-LWRs
Maintenance Rule	§ 52.79(a)(15)	Yes, also, see Reactor Coolant Pressure Boundary in Table 3 as applicable
Control of Effluents	§ 52.47(a)(10) § 52.79(a)(16)(i) § 52.137(a)(10)	Yes
Effluents Monitoring and Sampling Program	§ 52.79(a)(16)(ii)	Yes[14]
TMI Requirements	§ 52.47(a)(8) § 52.79(a)(17) § 52.137(a)(8)	Yes, see Table 4
Risk-Informed Categorization of SSCs	§ 52.79(a)(18)	Yes, (COL only)[15]
Emergency Plans	§ 52.79(a)(21)	Yes (COL only)
Multi-Unit Sites	§ 52.79(a)(31)	Yes (COL only)
Physical Security Plan	§ 52.79(a)(35)	Yes (COL only)
Safeguards Contingency Plan	§ 52.79(a)(36)	Yes (COL only)
Aircraft Impact Assessment	§ 52.47(a)(28) § 52.79(a)(47) § 52.137(a)(26)	Yes
Limited work authorization	§ 52.80(c)	Yes (COL only)

SSCs. Staff should review the use of these standards, incorporating the conditions in the regulations (such as those in section 50.55a(b)) as applicable to the design. The use of existing codes and standards, when relevant, can provide a recognized quality standard and alleviate much of the need to justify component quality on a more specific basis at the design stage.

[14] While § 52.79(a)(16)(ii) refers to Part 50, Appendix I, which is only applicable to LWRs, as being the source of the requirement for an effluent monitoring and sampling program, such a program is also necessary to satisfy the requirements of § 50.36a, which is applicable to all nuclear power reactors, to report annually the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous 12 months.

[15] Under § 50.69, COL holders may not transition to the use of risk-informed categorization of SSCs but must instead have elected to use § 50.69 during the application process. This is reflected in the requirements of § 52.79(a)(18) to include the necessary information in the COL application to reflect the desire to make voluntary use of the provisions of § 50.69. In SRM-SECY-18-0106, the Commission approved petition for rulemaking (PRM)-50-110 to consider extending the eligibility to transition to § 50.69 to COL holders in the ongoing Part 50/52 lessons learned rulemaking.

Table 2. Topic	Regulation	Applicability to non-LWRs
Mitigation of Beyond-Design-Basis Events	§ 52.80(d)	Yes (COL only)[16]

Table 3

Table 3 includes regulations, by part, other than those in 10 CFR Part 50 and Part 52 that may apply to non-LWRs at some stage in the licensing process. It lists regulations by 10 CFR citation, provides a brief description of the regulation, and lists applicability.

Table 3. Other regulations that may apply to non- LWRs[17]

Table 3. Regulation	Topic	Applicability to non-LWRs
10 CFR Part 2	Agency rules of practice and procedure	Yes
10 CFR Part 9	Public records	Yes
10 CFR Part 11	Criteria and procedures for determining eligibility for access to restricted data or national security information or an employment clearance	Yes
10 CFR Part 19	Notices, instructions and reports to workers: inspection and investigations	Yes
10 CFR Part 20	Standards for protection against ionizing radiation	Yes
10 CFR Part 21	Reporting of defects and non-compliance	Yes
10 CFR Part 25	Access authorization	Yes
10 CFR Part 26	Fitness for duty programs	Yes
10 CFR Part 30	Rules of general applicability to domestic licensing of byproduct material	Yes

[16] While the requirements of § 52.80(d) are limited to COL applicants, as noted in SECY-19-0066, “Staff Review of NuScale Power’s Mitigation Strategy for Beyond-Design-Basis External Events,” the design certification process can provide for finality under 10 CFR 52.63 and Section VI, “Issue Resolution,” of the standard formatting used for DC rules in the appendices to 10 CFR Part 52 for the adequacy of the SSCs to perform their mitigation strategies functions, as analyzed in the FSAR. Similar backfitting protection would be available under § 50.109 for standard designs approved by the staff under Subpart E to 10 CFR Part 52.
[15] Omission of any given regulation from the tables should not be interpreted as a non-applicability.

Table 3. Regulation	Topic	Applicability to non-LWRs
10 CFR Part 31	General domestic licenses for byproduct material	Yes
10 CFR Part 37	Physical protection of Category 1 and Category 2 quantities of radioactive material	Yes
10 CFR Part 40	Domestic licensing of source material	Yes
10 CFR Part 51	Environmental protection regulations for domestic licensing and related regulatory functions	Yes
§ 51.51 (section added for completeness)	Environmental fuel cycle environmental data	No
§ 51.52 (section added for completeness)	Environmental effects of transportation of fuel and waste	No
10 CFR Part 54	Requirements for renewal of operating licenses for nuclear power plants	Yes
10 CFR Part 55	Operators' licenses	Yes
10 CFR Part 70	Domestic licensing of special nuclear material	Yes
10 CFR Part 71	Packaging and transportation of radioactive material	Yes
10 CFR Part 72	Licensing requirements for the independent storage of spent nuclear fuel and high-level radioactive waste, and reactor-related greater than Class C waste	Yes
10 CFR Part 73	Physical protection of plants and materials	Yes
10 CFR Part 74	Material control and accounting of special nuclear material	Yes
10 CFR Part 81	Standard specifications for the granting of patent licenses	Yes

Table 3. Regulation	Topic	Applicability to non-LWRs
10 CFR Part 95	Facility security clearance and safeguarding of national security information and restricted data	Yes
10 CFR Part 100	Reactor site criteria	Yes
10 CFR Part 110	Export and import of nuclear equipment and material	Yes
10 CFR Part 140	Financial protection requirements and indemnity agreements	Yes
10 CFR Part 170	Fees for facilities, materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended	Yes
10 CFR Part 171	Annual fees for reactor licenses	Yes

Table 4

Requirements under 10 CFR 50.34(f) (i.e., Three Mile Island (TMI) requirements) are only applicable for 10 CFR Part 52 applications. See Footnote 4 on page **Error! Bookmark not defined.** of this Appendix for a discussion of applicability to 10 CFR Part 50 applicants. Applicants are required to demonstrate compliance with the technically relevant TMI items. Use of the term "technically relevant" in the text of the regulation allows for a greater degree of flexibility in meeting the regulation. If a sound argument can be made that the requirement in question is not technically relevant to a design under review, the requirement is satisfied without a need for an exemption. Table 4, below, provides generic applicability determinations for non-LWRs, with entry conditions for technical relevancy listed for some items. If the "entry conditions" are not met, then the regulations are considered not applicable. The 10 CFR 50.34(f) citations not listed in Table 4 are considered not applicable.

As part of the review of the 10 CFR 50.34(f) requirements, staff found instances where the requirement in Section 50.34(f) could partially duplicate other requirements for some applicants, conditional on compliance with other regulations. These regulations are marked with an asterisk (*) in the table below. For example, 10 CFR 50.34(f)(1)(i) requires, in part, that an applicant perform a plant/site specific probabilistic risk assessment to seek improvements in the reliability of heat removal systems. But an applicant for a COL also needs to meet Section 52.79(a)(46), which requires an applicant to provide a description of the design-specific probabilistic risk assessment (PRA) and its results. Likewise, 10 CFR 50.34(f)(3)(iii) requires in part that an applicant establish a quality assurance (QA) program based on a set of specified criteria, and an applicant for a CP/OL is also required to meet:

- 50.34(a)(7), which requires a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility;

- 50.34(b)(6) which requires an applicant provide information concerning the applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements, and managerial and administrative controls to be used to assure safe operation; and

- 10 CFR Part 50 Appendix B, which provides the QA criteria to be applied to the design, fabrication, construction, and testing of the SSCs of the facility.

Thus, an applicant may demonstrate compliance with Section 50.34(f) requirements in some cases by meeting other existing requirements and referencing the portions of the application that demonstrate how these other requirements are satisfied. In addition, the Commission approved a rulemaking plan to revise the regulations in 10 CFR Part 50 for new power reactor applications to more closely align with requirements in 10 CFR Part 52, incorporating the requirements identified by the staff in SECY-15-0002, including the technically relevant TMI-related items under 10 CFR 50.34(f) and the PRA requirements under section 50.71(h). Changes to those requirements as a result of that rulemaking may affect the classification below.

Table 4 - Applicability of 10 CFR 50.34(f) "TMI Requirements" to non-LWRs under Part 52

Table 4. Regulation	**Topic**	**Applicability to non—LWRs** (See above for discussion of *)
§ 50.34(f)(1)(i)	PRA to seek improvements in reliability of heat removal systems	*Yes
§ 50.34(f)(1)(iii)	Reactor coolant pump seal damage	Yes (entry condition: only for reactor designs that have a coolant pump with seals that retain inventory credited for core cooling)
§ 50.34(f)(2)(i)	Control room simulator	*Yes
§ 50.34(f)(2)(ii)	Plant procedure improvement program	Yes
§ 50.34(f)(2)(iii)	Control room human factors	Yes
§ 50.34(f)(2)(iv)	Safety parameter display system	Yes
§ 50.34(f)(2)(v)	Automatic indication of status of safety systems	Yes

Table 4. Regulation	**Topic**	**Applicability to non—LWRs** (See above for discussion of *)
§ 50.34(f)(2)(vi)	High point venting of reactor coolant system (RCS)	Yes (entry condition: only if reactor coolant flow is credited for core cooling and coolant flow can be impeded by noncondensible gases)
§ 50.34(f)(2)(vii)	Radiation shielding design review	Yes
§ 50.34(f)(2)(viii)	Post-accident sampling	Yes
§ 50.34(f)(2)(x)	Relief and safety valves	Yes (entry condition: only if RCS has relief valves and failure of these valves would lead to core cooling challenges)
§ 50.34(f)(2)(xi)	Relief and safety valves	Yes (entry condition: only if RCS has relief valves and failure of these valves would lead to core cooling challenges)
§ 50.34(f)(2)(xiv)	Containment isolation	Yes (entry condition: only for designs that use a traditional containment rather than a functional containment approach)
§ 50.34(f)(2)(xv)	Containment purging	Yes (entry condition: only for designs that use a traditional containment rather than a functional containment approach)
§ 50.34(f)(2)(xvii)	Control room instrumentation for containment functions	Yes (entry condition: only for designs that use a traditional containment rather than a functional containment approach)
§ 50.34(f)(2)(xviii)	Coolant instrumentation	*Yes
§ 50.34(f)(2)(xix)	Post-accident monitoring	Yes
§ 50.34(f)(2)(xxvi)	Leakage control outside containment	Yes (entry condition: only for designs that have SSCs capable of circulating radioactive materials resulting from an accident outside of qualified barrier(s) to radioactive release)
§ 50.34(f)(2)(xxvii)	In-plant Radiation Monitoring	Yes

Table 4. Regulation	**Topic**	**Applicability to non—LWRs** (See above for discussion of *)
§ 50.34(f)(2)(xxviii)	Preclude control room habitability issues during accidents	*Yes
§ 50.34(f)(3)(i)	Industry experience	Yes
§ 50.34(f)(3)(ii)	Quality assurance (QA) list includes all SSCs important to safety	Yes
§ 50.34(f)(3)(iii)	QA program	*Yes
§ 50.34(f)(3)(iv)	Dedicated containment penetrations	Yes (entry condition: only for designs that use a traditional containment rather than a functional containment approach)
§ 50.34(f)(3)(vi)	Containment	Yes (entry condition: only for designs with external hydrogen mitigation systems with a traditional containment)
§ 50.34(f)(3)(vii)	Management plan for design and construction activities	Yes

Table 5

Table 5 lists the regulations associated with three topical areas (fission product release, criticality monitoring, and reactor coolant pressure boundary) for which the underlying regulatory basis applies to all reactor designs, but the regulations contain language that is specific to LWR designs. A generic resolution for each of these items is currently complicated by design-specific considerations and the relative importance of each concept in the overall safety demonstration of the specific design. For this reason, the NRC staff anticipates that non-LWR applicants may request exemptions from these regulations, but the precise nature of each requested exemption will depend on the specific technology and how other regulations are being met. The NRC staff will engage with non-LWR applicants with the goal of affording applicants as much flexibility as possible in implementing solutions to meet the underlying purpose of these regulations. The staff emphasizes the importance of early engagement on these topics to facilitate an efficient and effective review.

Table 5 – Areas with anticipated exemptions

Topical Area	Regulation	Discussion
Fission Product Release	§ 50.34(a)(1)(ii)(D) § 52.47(a)(2)(iv) § 52.79(a)(1)(vi)	These provisions require that an applicant assume a fission product release from the core into the containment and that the applicant perform an evaluation and analysis of the postulated fission product release using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents. This language is LWR-centric and the prescriptive nature is not consistent with the Commission policy in staff requirements memorandum (SRM)-SECY-18-0096 that would allow functional containment for fission product retention rather than assuming that the facility would include a containment building. Further, the concept of core damage for a non- LWR design may differ dramatically from that normally described for an LWR design. These regulations still require an applicant to evaluate how it will mitigate the radiological consequences of accidents. Additionally, addressing the regulation will likely involve addressing defense-in-depth considerations.
Criticality Monitoring	§ 50.68(b) § 52.47(a)(17) § 52.79(a)(43) § 52.137(a)(17)	Regulations in 10 CFR 50.68(a) require that licensees meet the requirements in 10 CFR 70.24 or the requirements in 10 CFR 50.68(b). Paragraph (b) of 10 CFR 50.68 sets forth conditions for criticality safety based on the presence of borated or unborated water (and “low-density hydrogenous fluid”), i.e., LWR conditions, in lieu of monitoring to detect criticality. Non-LWR fuel differs significantly from traditional fuel types used in LWRs and in many cases has higher enrichment. The NRC staff recognizes that the requirements in 10 CFR 50.68(b) were added to provide clear methods for precluding criticality that would obviate the need for monitoring criticality in stored fuel and anticipates that non-LWR applicants could provide similar criteria for specific non-LWR fuel designs as necessary through exemptions. In the absence of an exemption, a non-LWR application will be required to describe criticality monitoring required by 10 CFR 70.24. The corresponding regulations in 10 CFR Part 52 that cite 10 CFR 50.68 would be included in the exemption, if applicable.

Topical Area	Regulation	Discussion
Reactor Coolant Pressure Boundary	§ 50.2 (Definitions – “Basic Component” and Safety-related structures, systems and components” § 50.36(c)(2)(ii) § 50.49(b) § 50.65 10 CFR Part 50, Appendix S	The reactor coolant pressure boundary for an LWR provides a fission product retention barrier for the release of radionuclides. However, in some non-LWRs, the reactor coolant boundary would not serve this function. Fission product retention is provided by the functional containment. Therefore, for these designs, the statement in 10 CFR 50.2 (2 instances), 10 CFR 50.49(b), and 10 CFR 50.65, “The integrity of the reactor coolant pressure boundary” is not necessary and an exemption is anticipated. In 10 CFR 50.36(c)(2)(ii), “significant abnormal degradation of the reactor coolant pressure boundary” is likewise not a safety consideration for some non-LWRs and can be replaced by “significant abnormal degradation of the functional containment” via an exemption. The corresponding regulations in 10 CFR Part 52 that cite 10 CFR Part 50 regulations to the left would also need to be included in the exemption if applicable. For simplicity, the 10 CFR Part 52 regulations are not included in the listing.

Table 6

Table 6 provides a list of the regulations in 10 CFR Part 50 and Part 52 that apply to all power reactors but reference a 10 CFR Part 50 regulation that refers specifically to LWRs. Because these regulations apply to all power reactors, non-LWR power reactor applicants seeking a permit, license, design certification, or standard design approval under 10 CFR Parts 50 or 52 would likely request exemptions from these requirements or could choose to demonstrate compliance. As noted above, in accordance with 10 CFR 50.12(a), the NRC upon its own initiative may evaluate and document exemptions to the regulations in this table. If the application contains the design information already required by NRC regulations to be included in the application, such information should form sufficient bases for these exemptions.

For Table 6 regulations, applicants may not need to include the exemption information described in the bullets listed on page 3 of this appendix. Instead, applicants could include a statement requesting an exemption to the items in Table 6 because the design is a non-LWR and therefore, not subject to the referenced Part 50 regulations. The staff may request that the applicant provide additional information on the docket, where necessary, to support exemptions that the staff may consider upon its own initiative. As part of the rulemaking to revise regulations in 10 CFR Part 50 for new power reactor applications to more closely align with requirements in 10 CFR Part 52, many of these requirements are being revised to better reflect applicability based on the underlying regulation.

Separately, the underlying safety purpose behind the concept of some of these regulations (e.g., ATWS) remains a consideration in the staff’s review in reaching an adequate protection finding. A non-LWR applicant may not need to comply with the prescriptive requirements listed in the table, but if a similar type of event could present a safety issue for a non-LWR design, the applicant may instead describe how the design either prevents or mitigates that event.

Table 6. Regulations Referencing Part 50 Regulations Limited to LWRs

Topical Area	Regulation	Discussion
Analysis of SSCs and ECCS Evaluation	§ 50.34(a)(4) § 50.34(b)(4) § 52.47(a)(4) § 52.79(a)(5) § 52.137(a)(4)	These regulations apply to all power reactors. The second sentence of each provision requires a description of the analysis and evaluation of the ECCS cooling performance in accordance with 10 CFR 50.46, which is only applicable to LWRs.
Anticipated Transient Without Scram (ATWS)	§ 52.47(a)(15) § 52.79(a)(42) § 52.137(a)(15)	These regulations apply to all power reactors. These provisions reference 10 CFR 50.62, which is only applicable to LWRs.
SBO	§ 52.47(a)(16) § 52.79(a)(9) § 52.137(a)(16)	These regulations apply to all power reactors. These provisions reference 10 CFR 50.63, which is only applicable to LWRs.
Pressurized Thermal Shock Events	§ 50.34(b)(9) § 52.47(a)(14) § 52.79(a)(7) § 52.137(a)(14)	These regulations apply to all power reactors. These provisions require a description of protection against pressurized thermal shock events and reference 10 CFR 50.60 and/or 10 CFR 50.61, which are only applicable to LWRs. All non-LWR designs the NRC staff is aware of operate at conditions that do not support pressurized thermal shock events.
Containment Leak Rate	§ 52.79(a)(12)	These regulations apply to COLs for all power reactors. The regulation references 10 CFR Part 50 Appendix J, which is only applicable to LWRs.
Reactor Vessel Surveillance Program	§ 52.79(a)(13)	These regulations apply to COLs for all power reactors. The regulation references 10 CFR Part 50 Appendix H which is only applicable to LWRs.
Effluent Monitoring and Sampling Program	§ 52.79(a)(16)(ii)	These regulations apply to all power reactors. The regulation references 10 CFR Part 50 Appendix I which is only applicable to LWRs.

Attachment: Examples Demonstrating Regulatory Compliance and Exemptions

A regulation with "Yes" in the last column of Tables 1 through 3 of Appendix B of this document is generically applicable to non-LWRs and applications will need to include information to demonstrate on a design-specific basis that (1) the proposed design complies with the regulation in question or (2) the application provides technical justification for an exemption from the regulation. The application should contain information to address the regulations in the manner chosen by the applicant, and the NRC encourages interaction with the staff to align on any areas where information is not initially clear. Some examples of how non-LWR applicants might address specific regulations follow.

Regulatory Compliance

In many cases, the regulations are written such that any reactor applicant – LWR or non-LWR – will be able to explain how the regulation in question is met. Often, this is clear; for other regulations, the distinction between whether compliance is achieved or whether an exemption is needed may be less clear. In order to provide additional clarity, the NRC staff provides the following examples for the level of detail acceptable to the staff for justifying compliance with a set of regulations:

- 10 CFR 50.55a(a) provides a list of codes and standards approved for incorporation by reference into NRC regulations but does not itself impose requirements. It is applicable to non-LWRs. Regulations in 10 CFR 50.55a(b)-(h) and (z) prescribe the use of the codes, but only 10 CFR 50.55a(h) and (z) are applicable to non- LWRs. A designer of a non-LWR or applicant for a license for a non-LWR design may elect to apply the provisions of the American Society of Mechanical Engineers (ASME) Code, OM Code, or ASME NQA-1, but § 50.55a does not impose those provisions on non-LWR designs, even if incorporated by reference into 10 CFR 50.55a. Alternatively, an applicant could choose to request to apply an international standard or develop its own standards, which it would have to technically justify. For standards listed as requirements in 10 CFR 50.55a that do not apply to non-LWR designs (see Table 1 above), no action is required; for those that do, compliance is required.

- 10 CFR 50.46a requires in part that:

  "Each nuclear power reactor must be provided with high point vents for the reactor coolant system, for the reactor vessel head, and for other systems required to maintain adequate core cooling if the accumulation of noncondensible gases would cause the loss of function of these systems."

  By its plain text, the regulation is applicable to "each nuclear power reactor" regardless of reactor technology. However, high point vents for the reactor coolant system need only be supplied if the accumulation of noncondensible gases could cause the loss of function of the systems required to maintain adequate core cooling. Accordingly, to demonstrate compliance with this regulation, an applicant can either:

  - Provide high point vents for the reactor coolant system, the reactor vessel head (if applicable), and other systems required to maintain adequate core cooling, or

- Provide a justification that noncondensible gases cannot cause a loss of function for the above systems. For some non-LWR designs, this justification might be straightforward (e.g., those with a low pressure reactor coolant system and an external core cooling system not susceptible to gas binding) and therefore involve a simple statement in the application with a reference to the appropriate system technical description. For other non-LWR designs, this justification might be more involved and call for additional description in the application.

- 10 CFR 50.44 governs the requirements associated with combustible gas control. Sections 50.44(a) through (c) apply only to water-cooled reactor designs, but 10 CFR 50.44(d) also applies to non-water-cooled reactor applicants and provides that applications subject to Section 50.44(d) must include:

  (1) Information addressing whether accidents involving combustible gases are technically relevant for their design, and

  (2) If accidents involving combustible gases are found to be technically relevant, information (including a design-specific probabilistic risk assessment) demonstrating that the safety impacts of combustible gases during design-basis and significant beyond design-basis accidents have been addressed to ensure adequate protection of public health and safety and common defense and security.

  All non-LWR applications must contain information to address the technical relevance of accidents involving combustible gases to the safety of the design. The extent of this information will depend on the specific design. For some non-LWR designs, if combustible gases cannot be generated by any means, a short statement to that effect coupled with any necessary references to supporting technical material could be sufficient to address the regulation. As the relevance of combustible gases to the design increases, additional information becomes necessary to meet the regulation (up to safety and risk assessments associated with combustible gases during accident conditions).

- 10 CFR 52.79(a)(4)(i) requires that applicants provide PDC for the facility, and further states that Appendix A to Part 50, "General Design Criteria for Nuclear Power Plants," provides guidance to applicants in establishing principal design criteria for types of nuclear power units other than water-cooled reactor designs similar to those for which the Commission has previously issued a construction permit. The preamble to 10 CFR Part 50, Appendix A states that the GDC are also considered to be generally applicable to these other types of nuclear power units.

  In satisfying the requirement that an application include PDC, applicants should consider the concepts of the existing GDC in Appendix A as guidance as noted in the regulation. One acceptable means of considering this guidance is through use of RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors." RG 1.232 is guidance, and as such represents only one means for satisfying the regulation. If an applicant elects not to consider RG 1.232 in developing its PDC, it should ensure it has adequately addressed the safety concepts described in 10 CFR Part 50, Appendix A, as applicable to the applicant's specific reactor technology. In particular, several of the existing GDC are not technology-specific (such as Criteria 1-5, Protection by Multiple Fission Product Barriers, Protection and Reactivity Control

Systems), and applicants should provide PDC that address these concepts.

- 10 CFR 52.79(a)(6) requires that the application contain a description and analysis of the fire protection design features for the reactor necessary to comply with 10 CFR Part 50, Appendix A, GDC 3, and 10 CFR 50.48. The requirements associated with Section 50.48 are applicable, and while compliance with GDC 3 itself is not a requirement, staff anticipates that applicants will provide a PDC that is representative of Criterion 3 or provide justification for not doing so (consistent with the discussion regarding PDC previously). Section 52.79(a)(41) does not require non-LWR applicants to evaluate the proposed facility againstNUREG-0800. Nonetheless, SRP Section 9.5.1 provides staff review guidance that is, in large part, technology neutral for helping the staff determine whether fire protection objectives are met. Accordingly, evaluation in the application of the proposed facility against SRP Section 9.5.1 and identification of differences in design features, analytical techniques, and procedural measures proposed for a facility and the corresponding design features, analytical techniques, and procedural measures described in the SRP would assist the staff in its review.

<u>Exemptions</u>

- For emergency response, emergency preparedness, and emergency planning zone regulations (e.g., those in 10 CFR 50.33(g), 50.47(b), 50.47(c)(2), and Part 50, Appendix E), existing requirements may not account for design-specific features for some non-LWR designs. The staff will not describe here the specific portions of the regulations from which an applicant might take an exemption (those will be up to an applicant to select and justify), but such topics may include a reduced emergency planning zone, changes to offsite emergency response, or other specific exemptions from those regulations.

  Because the NRC understands that the existing emergency planning regulations may not fully account for design features for new reactor technologies, the staff, as part of ongoing regulatory efforts, has undertaken a rulemaking entitled “Emergency Preparedness for Small Modular Reactors and Other New Technologies” (85 FR 28436, docket ID NRC-2015-0225). In the SRM for SECY-15-0077 “Options for Emergency Preparedness for Small Modular Reactors and Other New Technologies” (ADAMS Accession No. ML15216A492) (SECY-15-0077 is available at ADAMS Accession No. ML15037A176), the Commission stated, “[f]or any small modular reactor [(SMR)] reviews conducted prior to the establishment of a rule, the staff should be prepared to adapt an approach to emergency planning zones for SMRs under existing exemption processes, in parallel with its rulemaking efforts.” Exemptions that conform to this proposed rule will be evaluated on a case-by-case basis and, use of the proposed rule to inform the exemption can streamline the exemption request process.

Accordingly, the staff expects many non-LWR applicants to apply for exemptions from portions of the current emergency preparedness regulations. In order to facilitate an efficient review of these exemptions, applicants should provide the following as part of their exemption requests (keeping in mind the general exemption content guidance above:

- Specifically identify the portions of the regulations from which the applicant is requesting an exemption (either by citing regulatory text or striking through text from which the applicant proposes an exemption).

- A description of how the exemption request satisfies the regulatory acceptance criteria associated with the request (e.g., Section 50.12). This description would need to include a description of how the exemption is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security. Further, special circumstances must be present; of the listed special circumstances, staff expects most applicants to cite that "[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule." (This is one example; exemption requests may be based on other special circumstances.)

- For exemption requests of this nature, applicants should provide a consequence- and risk-oriented justification, including a quantitative assessment of the dose at the proposed emergency planning zone boundary. See 85 FR 28436 (describing the performance-based approach in the proposed rule "Emergency Preparedness for Small Modular Reactors and Other New Technologies.")

- Current NRC regulations include definitions that align with LWR technology, and some non-LWR designs may have design features that do not align with current regulatory definitions or are distinct in terms of safety importance from similar features in LWRs. One example is in the definition of safety-related SSCs in which one set of safety-related SSCs is defined as those which are relied upon to remain functional following design-basis events to assure "(1) the integrity of the reactor coolant pressure boundary." Some non-LWRs do not have a reactor coolant pressure boundary, while others have a coolant pressure boundary that does not or only partially performs any safety function. Applicants for licenses for these designs may need to request exemptions from this definition.

  Because the definition itself does not directly impose any regulatory requirements and the definition is then used in a variety of different regulations that do impose requirements, an exemption from the definition is complex. In the case of the definition of "safety-related" SSCs, an applicant has another option besides requesting an exemption: the applicant could follow the process laid out in 10 CFR 50.69 to classify the system as Risk-Informed Safety Class (RISC) 3, safety-related but performing low safety significant functions (or possibly RISC-4). Alternately, in taking an exemption from this definition, an applicant should (continuing to consider the general exemption content guidance above):

  - Clearly define the scope of the requested exemption – evaluate what portions of the definition do or do not apply to the design, then provide a revised definition that will apply. It is helpful to include any technical references to relevant portions of the application.

- Evaluate how changing the definition affects regulatory requirements that apply to the design. In this case, as an example reviewing 10 CFR Part 50, the safety- related SSC definition affects the following:

  - Section 50.10, Limited work authorizations
  - Section 50.49, Environmental qualification of electric equipment
  - Section 50.55a, Codes and standards
  - Section 50.65, Maintenance rule
  - Section 50.69, Risk-informed categorization of SSCs
  - Section 50.72, Immediate notification requirements
  - Section 50.73, License event report system
  - Appendix B
  - Appendix S

  These may or may not all apply to a given application – an applicant should review all applicable regulations (not just Part 50) for applicability to its design or facility. The staff can clarify the effect of an exemption from a definition on applicable requirements in pre-application engagement. If a current NRC regulation applies to its design, an applicant should evaluate how requesting an exemption from the definition, e.g., of "safety-related SSC," affects the requirements of that regulation.
- Provide a description of how the exemption request satisfies the regulatory requirements associated with the request (e.g., Section 50.12), considering both the definition and any of the regulations mentioned above (e.g., by justifying how application of the regulation in the particular circumstances associated with the design would not serve the underlying purpose of the rule).
- Finally, it is helpful, as part of the discussion of the "special circumstances" demonstration, for an applicant to provide in its technical justification a discussion of the safety significance of the proposed exemption. Such a discussion could include how the proposed exemption is justified for the design, either by demonstrating that the safety significance of the reactor coolant boundary is sufficiently low considering the other portions of the safety-related definition and any of the affected regulations, or by providing alternate acceptable reasoning for the exemption (i.e., that the design in question does not have a reactor coolant system with a pressure boundary).

- In some cases, non-LWR designs may include margins of safety that, in the applicant's view are sufficient to address specific event-based regulatory requirements without providing for additional design features beyond those incorporated into the design. An example of where this might be relevant is 10 CFR 50.155(b)(2), which requires in part that each applicant or licensee shall develop, implement, and maintain strategies and guidelines to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities under the circumstances associated with loss of large areas of the plant impacted by the event, due to explosions or fire, including firefighting, operations to mitigate fuel damage, and actions to minimize radiological release.

In the case of this specific regulation, an applicant would have the option of compliance through implementing a relatively simple set of strategies and guidelines that demonstrate that core cooling, containment, and spent fuel pool cooling capabilities are maintained. Nonetheless, an exemption could be justified if the loss of large areas of the plant do not result in dose consequences despite the failure of SSCs to perform their safety functions. In appropriate circumstances, an applicant may wish to seek an exemption from this regulation. Staff anticipates an exemption request to this effect would include the following:

- A clear exemption request, with the application providing the portions of the regulation that are applicable and to which the exemption request applies. Staff anticipates an exemption request of this nature would involve substantial technical justification, though not necessarily as part of the exemption itself – any exemption to this effect would be inextricably tied to the overall safety of the design and thus would be expected to reference other portions of the application.

- A description of how the exemption request satisfies the regulatory requirements associated with the request (e.g., Section 50.12). Staff anticipates that the special circumstance cited could be to demonstrate application of the regulation in the particular circumstances associated with the design would not be necessary to serve the underlying purpose of the rule.
- In addressing the special circumstances justifying the exemption, the applicant's justification could demonstrate that strategies and guidelines are not necessary for the loss of large areas because the public health consequences of a loss of large areas of the plant are bounded by an analysis already conducted for another event, with appropriate justification and reference to that event.

APPENDIX C - Construction Permit Guidance

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) staff is providing this guidance to facilitate the safety review of construction permit (CP) applications for non-light water reactors (non-LWRs). Note that this Construction Permit Guidance Section is a follow-on to a white paper on the topic. The draft white paper "Safety Review of Power Reactor Construction Permit Applications" can be found in Agencywide Documents Access and Management System (ADAMS) Accession No. ML21043A339. The white paper included CP guidance for both light water reactors (LWRs) and non-LWRs. The NRC staff subsequently determined that it was best to split the CP guidance into separate guidance for LWRs and non-LWRs. However, the staff recognizes that there is a portion of the white paper guidance that is applicable to both types of designs.

Portions of the guidance that are applicable to both LWRs and non-LWRs are shown in italics below. The italicized text is quoted from guidance found in DNRL-ISG-2022-01, "Safety Review of Light-Water Power Reactor Construction Permit Applications," dated October 2022 (ADAMS Accession No. ML22189A099).

GUIDANCE

This ISG discusses some of the regulatory requirements for a CP, applicable review guidance in the SRP [Standard Review Plan, NUREG-0800 available at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/index.html]*, and special topics related to CP applications. The appendix to this ISG supplements the SRP by clarifying the review of certain information in a CP application.*

Requirements for a Power Reactor Construction Permit Application

A number of regulations apply to a power reactor CP application, including but not limited to the following:

- *10 CFR 50.30, "Filing of application; oath or affirmation"*
- *10 CFR 50.33, "Contents of applications; general information"*[1]
- *10 CFR 50.34, "Contents of applications; technical information," particularly 10 CFR 50.34(a) on the PSAR* [preliminary safety analysis report]
- *10 CFR 50.34a, "Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors"*
- *10 CFR 50.35, "Issuance of construction permits"*
- *10 CFR 50.40, "Common standards"*
- *10 CFR 50.46, "Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors"*
- *10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses"*
- *10 CFR 50.55a, "Codes and standards"*
- *10 CFR 50.150, "Aircraft impact assessment"*
- *10 CFR Part 20, "Standards for Protection against Radiation"*

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[1] *Although referenced herein, guidance on compliance with the applicable requirements in 10 CFR 50.30 and 10 CFR 50.33 is outside the scope of this document.*

- *10 CFR Part 100, "Reactor Site Criteria"*

The following discussion elaborates on certain CP requirements.

The regulations in 10 CFR 50.34(a) specify the minimum technical information in the PSAR accompanying a CP application, including preliminary design information and a description and safety assessment of the site on which the facility is to be located. As required by 10 CFR 50.34(a)(3), the preliminary design information must include the principal design criteria, the design bases and an explanation of how the design bases relate to the principal design criteria, and information on the materials of construction, general arrangement, and approximate dimensions sufficient for the staff to conclude that the final design will conform to the design bases with an adequate margin for safety. In accordance with 10 CFR 50.34(a)(1)(ii), the application must provide a description and safety assessment of the site and a safety assessment of the facility, and the Commission expects that reactors will reflect through their design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products.

The regulations in 10 CFR 50.34a require a description of the preliminary design of equipment to maintain control of radioactive material in effluents produced during normal reactor operations, and of the design objectives and means for keeping the levels of radioactive material in effluents as low as is reasonably achievable. Furthermore, 10 CFR 50.34a requires a CP application to estimate the kinds and quantities of the principal liquid and gaseous radionuclides that would be released to unrestricted areas during normal reactor operations and to describe the provisions for packaging and storing radioactive solid waste materials and shipping them off site.

The regulations in 10 CFR 50.150 require CP applicants to perform a realistic design-specific assessment of how the impact of a large commercial aircraft would affect the facility and to identify and incorporate into the design those design features and functional capabilities that show that (with reduced operator actions) the criteria in 10 CFR 50.150(a)(1)(i)–(ii) are satisfied. SRP section 19.5, "Adequacy of Design Features and Functional Capabilities Identified and Described for Withstanding Aircraft Impacts," provides guidance acceptable to the staff for performing the licensing review. Note that 10 CFR 50.150 requires applicants to perform aircraft impact assessments at both the CP and OL [operating license] *stages and include the required information in both applications, based on the level of design information available at the time of each application. The NRC's decision on an application subject to 10 CFR 50.150 will be separate from any NRC determination that may be made with respect to the adequacy of an impact assessment, which is not required to be submitted to the NRC (74 FR 21820; June 12, 2009).* [Note: additional aircraft impact assessment guidance can be found in the advanced reactor section below.]

Issuance of a Construction Permit
The NRC may issue the CP if the agency makes the findings listed in 10 CFR 50.35(a). Pursuant to 10 CFR 50.35(b), a CP authorizes the applicant to proceed with construction but will not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests and receives such approval and such approval is incorporated in the permit. While 10 CFR 50.35 provides some flexibilities for applicants, this does not obviate the other requirements applicable to a CP, such as those in 10 CFR 50.34(a). The CP application will need to include sufficient information for the staff to conduct its review and evaluate the information against the applicable regulations.

In its early practices, the predecessor to the NRC, the Atomic Energy Commission, issued a "provisional" CP when an applicant had not submitted all the technical information necessary to complete the application and to approve all proposed design features. However, almost all issued "provisional" CPs were never converted to a "final" CP but were instead merged into an OL. Therefore, the Atomic Energy Commission proposed codifying the Commission's practice for issuing a CP (34 FR 6540; April 16, 1969). The final amendment to the regulations in 10 CFR 50.35 eliminated the term "provisional" CP, but the criteria in 10 CFR 50.35(a) for issuing a CP remained the same as the criteria used to issue the former "provisional" CPs (35 FR 5317; March 31, 1970). Historically, when issuing a power reactor CP under 10 CFR 50.35(a), the Commission authorized the construction of the facility described in the application and hearing record in accordance with the principal architectural and engineering criteria and the commitments identified therein.[2]

The current regulations for issuing a CP in 10 CFR 50.35(a) have not been modified since 1970:

> *(a) When an applicant has not supplied initially all of the technical information required to complete the application and support the issuance of a construction permit which approves all proposed design features, the Commission may issue a construction permit if the Commission finds that (1) the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public; (2) such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report; (3) safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and that (4) on the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.*
>
> *Note:*
> *When an applicant has supplied initially all of the technical information required to complete the application, including the final design of the facility, the findings required above will be appropriately modified to reflect that fact.*

If a novel design has not sufficiently progressed and certain information is not available at the time of CP application submittal, the PSAR should provide the criteria and bases that will be used to develop the required information, the concepts and alternatives under consideration, and the schedule for completing the design and providing the missing information. In general, the PSAR should describe the preliminary design of the facility in sufficient detail to enable the NRC staff to evaluate whether the facility can be constructed and operated without undue risk to

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2 *An example is the CP issued for the Shearon Harris Nuclear Power Plant* [Correspondence from Roger S. Boyd, "Issuance of Construction Permits—Shearon Harris Nuclear Power Plant, Units 1, 2, 3 and 4," January 27, 1978 (ML020560123)]. *CPs also included permit conditions on specified issues.*

public health and safety. The CP application must address all regulatory requirements applicable to a CP.

The required findings in 10 CFR 50.35(a) focus on the safety aspects of the design, including the principal architectural and engineering criteria and safety design features, and siting information to support construction of the facility. As 10 CFR 50.35(a) states, these findings were written for an application that does not contain sufficient information for the NRC to approve all proposed design features. Given the technological advances since the most recent amendment of the regulation, an applicant may provide more complete technical information in its CP application than was historically presented and thereby reduce the regulatory review in the subsequent OL review phase. As noted in 10 CFR 50.35(a), if specifically requested by the applicant, the findings in 10 CFR 50.35(a) will be modified for a complete CP application that provides all technical information, including the final design of the facility.

Under 10 CFR 50.35(b), a CP applicant may also request approval of any design features or specifications in its CP application, including new or novel design features or unique specifications.[3] *Any request for approval would need more than preliminary information to support the NRC staff's review to approve such design features or specifications. In such a case, the NRC expects that the level of design information available in the application to support the approval of a proposed design feature would be the same level of design information available for a 10 CFR Part 52 COL application. RG [Regulatory Guide] 1.206*[, "Applications for Nuclear Power Plants,"] *contains guidance on the level of design information that the NRC expects to be available to support a COL application. Any approval, if granted, would apply only to the extent that the item is fully addressed or treated in the application and would not extend beyond items or details not fully covered therein. The regulation in 10 CFR 50.35(b) clarifies that a CP authorizes the applicant to proceed with construction but is not an approval of the safety of any design features or specifications unless the applicant requests such approval and the approval is incorporated into the permit.*

As described in 10 CFR 50.35(c), the NRC will not issue a license authorizing operation of any facility until (1) the applicant submits, as part of an OL application, its FSAR [final safety analysis report] *and (2) the Commission finds that the final design provides reasonable assurance that operation of the facility in accordance with the requirements of the license and NRC regulations will not endanger public health and safety. The FSAR submitted with the OL should describe in detail the final design of the facility as constructed; identify the changes from the criteria, design, and bases in the PSAR; and discuss the bases and safety significance of the changes from the PSAR. Before issuing an OL, the NRC staff will review the applicant's final design in the FSAR to determine whether it has met all the Commission's safety requirements. If the NRC determines that all applicable requirements are met, the Commission will issue an OL permitting the applicant to operate the facility in accordance with the terms of the OL and the Commission's regulations under continued oversight by the NRC staff. Commission procedures include an opportunity for public hearings before the authorization of either facility construction or operation and a mandatory hearing before issuance of a CP.*

<u>*Special Topics*</u>

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[3] [*The special topics section of this ISG discusses preapplication activities that have proven effective and essential in gaining an early understanding of the applicant's plans and its proposed facility design, supporting early feedback on and staff review of unique design aspects of the facility, and preparing resources for the application review.*][Note this footnote is not applicable for non-LWR guidance]

This section discusses the relationship between the CP and OL reviews; the purposes and benefits of preapplication activities; the lessons learned from recently issued nonpower reactor CPs; the approach for reviewing concurrent license applications and applications incorporating prior NRC approvals; the potential effect of ongoing regulatory activities on CP reviews; and the licensing requirements for byproduct, source, or special nuclear material.

Relationship between the Construction Permit and Operating License Reviews

The approach to reviewing a CP application is intended to differ from the more recent COL [combined license] *application reviews in which an applicant provides all technical information on the final facility design to support the Commission's findings for issuance of a COL under 10 CFR Part 52. As discussed in the original proposed 10 CFR Part 52 rule (53 FR 32060; August 23, 1988), the licensing process in 10 CFR Part 50—*

> *was structured to allow licensing decisions to be made while design work was still in progress and to focus on case-specific reviews of individual plant and site considerations. Construction permits were commonly issued with the understanding that open safety issues would be addressed and resolved during construction, and that issuance of a construction permit did not constitute Commission approval of any design feature. Consequently, the operating license review was very broad in scope.*

Therefore, the NRC staff's review and evaluation of the proposed design of a facility provided in a CP application constitutes the first stage of a review that begins with the design, construction, and operating features described in the applicant's PSAR. The plant design and operating features may be preliminary when construction begins, with NRC evaluation of the final design, including the FSAR-level of design detail describing the facility as constructed, occurring during the review of the subsequent OL application. Consistent with recently issued CPs, CP conditions of a confirmatory nature focus on the additional information needed to address certain matters related to the safety of a final design and require the applicant to submit periodic reports on such information to the NRC before construction is completed.

Purposes and Benefits of Preapplication Activities

Preapplication activities have proven effective and essential for gaining an early understanding of the applicant's plans and its proposed facility design, supporting early feedback on and staff review of issues associated with the resolution of unique design aspects of the facility, and preparing resources for the application review. These interactions were key for the recently issued permits for the construction of medical radioisotope facilities as NPUFs [non-power production or utilization facilities] *licensed under 10 CFR Part 50. Insights gained from such interactions may bridge gaps in the existing SRP review guidance for particular facility designs.*

The staff has developed a draft white paper to provide information to advanced reactor developers on the benefits of robust preapplication engagement in order to optimize application reviews. The staff is in the process of capturing this white paper in ARCAP [advanced reactor content of applications project] *guidance. Although directed to the advanced reactor community, the preapplication engagement guidance, when issued as final as part of the ARCAP guidance development process, may be relevant to LWR license applicants and, if fully executed, will enable the NRC staff to offer more predictable and shorter schedules and other benefits when reviewing a reactor license application.* [Note: the content of the preapplication white paper described in this paragraph can be found in Appendix A of this document.]

Consistent with regulatory requirements and Commission policy statements, the NRC staff is more fully integrating the use of risk insights into preapplication activities by aligning its review focus and resources to risk-significant structures, systems, and components (SSCs) and other aspects of the design that contribute most to safety and thereby enhance the efficiency of the review process.

Lessons Learned from Recently Issued Construction Permits

As noted above, the NRC has issued CPs for two NPUFs licensed under 10 CFR Part 50: (1) SHINE Medical Technologies, in February 2016 [ML16041A471]*, and (2) Northwest Medical Isotopes, in May 2018* [ML18037A468]*. The NPUF lessons learned, which are described below, may improve the effectiveness and efficiency of safety reviews of PSARs to determine whether an application meets the 10 CFR 50.35 requirements for issuing a CP and other regulations applicable to a CP. However, those drawing lessons from recent NPUF reviews should consider the different technologies involved and the much more limited set of safety requirements that apply to an NPUF as opposed to a power reactor.*

Lessons learned from the review of these NPUF CP applications include the following:

- *Preapplication engagement is key to providing near-term guidance to the applicant.*
- *Early interactions support a common understanding of the information needed in the PSAR and the information that could reasonably be left for the FSAR accompanying the OL application, such as descriptions for programs implemented during operation.*
- *If the PSAR includes preliminary descriptions of the facility's SSCs, the NRC staff may accept and approve the application with regulatory commitments from the applicant to provide complete information in its OL application.*
- *The NRC staff's CP safety review is focused on ensuring the appropriate use of analysis methodologies to meet the requirements in the regulations.*

In the safety evaluations related to the CPs issued, the NRC staff noted the applicant's regulatory commitments for the resolution of items that were not necessary for the issuance of a CP, but that the applicant should address in the FSAR submitted with an OL application. CP conditions of a confirmatory nature focused on additional information needed to address certain matters related to the safety of the final design and required the applicant to submit periodic reports on such information to the NRC before construction is completed.

The NRC staff should consider the lessons learned in its approach to the review of a reactor CP application and be mindful of the different regulations applicable to a power reactor and the existing NRC staff review guidance in the SRP as supplemented by this ISG.

Concurrent Applications

A CP application may be accompanied by an application for an LWA [limited work authorization]*. For the LWA review, the NRC staff should refer to the guidance in RG 1.206, Revision 1, related to the definition of construction and LWAs.*

Questions have been raised about the possibility of submitting an OL application before the NRC issues a CP. The NRC staff is still considering the legal, policy, and timing implications of this action. For OL applications submitted before a CP is issued, the NRC would need to *develop a process to address the CP mandatory hearing (if not completed before submittal of the OL application) and the logistics associated with the OL hearing opportunity.*

The NRC staff notes the inherent complications associated with concurrent CP and OL reviews. For example, as a result of the OL review, a need to reclassify SSCs (i.e., from not safety-related to safety-related) could arise based on updated design information that was not available at the time of submittal of the CP application. In such a case, addressing this reclassification would result in an extensive reworking of both the CP and OL applications.

Construction Permit Application Incorporating Prior NRC Approvals

A CP application may incorporate prior NRC approvals by reference, including a standard design approval (SDA), a DC [design certification]*, or an ESP. Each of these approvals is supported by an NRC staff safety evaluation concluding that the applicant has met the specific regulatory requirements for approval and may be subject to conditions and additional requirements and restrictions. These prior NRC approvals finally resolve matters within their scopes when referenced in a CP application, as defined by the issue finality provisions for the particular 10 CFR Part 52 approval.*
If the NRC staff determines that the CP application satisfies the standards for referencing a prior NRC approval, including compliance with any associated conditions and additional requirements and restrictions, the NRC staff's CP review with regard to the referenced material would generally be limited to an evaluation of (1) how the CP application addresses the referenced approval conditions and additional requirements and restrictions, and (2) any departures or variances from the referenced material that are subject to prior NRC review. The NRC staff's CP review will focus on the portions of the application not previously approved by the NRC.

For a CP application referencing an ESP [early site permit]*, the NRC staff's review and evaluation would include a safety review and evaluation of the proposed design of the facility, any requested variances from the ESP, the satisfaction of any relevant permit conditions, and the update of emergency preparedness information in accordance with 10 CFR 52.39(b). As provided by 10 CFR 52.24(b), any ESP terms or conditions that cannot be met by CP issuance must be set forth as terms or conditions of the CP.*

For a CP application referencing an SDA or a DC, the NRC staff's review and evaluation may focus on the suitability of the selected site for the referenced design, satisfaction of any additional requirements or restrictions for the approved design, and any design matters outside the scope of the referenced design. Under 10 CFR Part 52, a DC must be based on an essentially complete design, while an SDA may approve only major features of the design. This difference may affect the level of design information that the CP application might need to include. Furthermore, Section IV.B in all issued DC rules provides that "[t]he Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50." The NRC discusses the basis for this restriction in the final rule for the U.S. Advanced Boiling Water Reactor DC (62 FR 25800; May 12, 1997).

For a CP application referencing an ESP and an SDA or a DC, the NRC staff's review and evaluation would generally focus on whether the referenced design fits within the characteristics of the approved site; whether the other applicable conditions, requirements, and restrictions in the referenced approvals are satisfied; whether departures or variances from the referenced approvals that require prior NRC approval comply with NRC regulations; and whether requirements for matters outside the scope of the referenced approvals are met.

Ongoing Regulatory Activities

The NRC is currently pursuing the alignment of requirements in 10 CFR Part 50 and 10 CFR Part 52 through rulemaking consistent with Commission direction described in SRM-SECY-15-0002, "Staff Requirements—SECY-15-0002—Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," dated September 22, 2015. This rulemaking is in its initial phases and may include additional licensing requirements for applications submitted under 10 CFR Part 50 (e.g., risk information). The NRC staff should continue to monitor the progress of the 10 CFR Part 50 and 10 CFR Part 52 rulemaking, as a CP applicant must comply with the applicable regulations in effect at the time the NRC issues the CP.

Receipt, Possession, and Use of Source, Byproduct, and Special Nuclear Material

This ISG does not provide review guidance on the licensing requirements for byproduct, source, or special nuclear material under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material;" 10 CFR Part 40, "Domestic Licensing of Source Material;" or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The CP applicant may address the applicable materials licensing requirements with its CP application (in accordance with 10 CFR 50.31, "Combining applications") or separately from the CP application, which was the historical practice.

Detailed Non-Light Water Reactor Construction Permit Guidance

Application Guidance

This portion of the CP content guidance is intended for CP applications involving non-LWRs. The guidance is based on an application using a risk-informed performance-based approach. Applicants are not required to utilize the Technology Inclusive Content of Application Project (TICAP)/licensing modernization project (LMP) approach described in Draft Regulatory Guide DG-1404, "Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors" (ML22076A003). Instead, applicants may use another methodology (e.g., traditional deterministic approach, maximum hypothetical accident[4]) to analyze non-LWR performance and develop a licensing basis. The TICAP/LMP process forms the basis for this guidance, although in some areas the guidance provides additional considerations for acceptably addressing a specific topic when a TICAP/LMP approach is not used. As noted above, applicants are encouraged to use the preapplication process to optimize reviews, which is especially important if an applicant intends to use a process other than the LMP to develop its licensing basis. Regardless, the review guidance in this document is limited in scope. NRC staff should continue to consult other established guidance documents, as applicable, to complete reviews of non-LWR applications.

[4] In this context, "maximum hypothetical accident" refers to a conservatively assessed, deterministic accident with consequences that bound the full spectrum of accident conditions for the plant and is not necessarily a credible event. The NRC encourages applicants seeking to use methodologies other than the LMP methodology to engage with the staff in pre-application discussions on the applicant's intended use of this approach for developing the content of its application.

Staff Review Guidance

This guidance addresses the minimum information necessary in a CP application for the staff to make the findings for a CP under 10 CFR 50.35(a). Under 10 CFR 50.35(a), when the applicant has not supplied all of the technical information required to support the issuance of a CP that approves all proposed design features, the Commission may issue a CP provided that the Commission makes the findings identified in that section. The CP applicant may also provide the technical information necessary to support approval of specific design features or specifications (i.e., request finality for the approved design features) in accordance with 10 CFR 50.35(b). When making its safety finding regarding the issuance of a CP under 50.35(a), the staff should determine whether the application:

- Describes the proposed design of the facility, including, but not limited to,
  - the principal architectural and engineering criteria for the design, and
  - the major features or components incorporated therein for the protection of the health and safety of the public.

- Omits information from the safety analysis that can reasonably be left to be considered later and will be provided in the FSAR.

- Describes safety features or components, if any, which require research and development program necessary to resolve any safety questions associated with such features or components.

- Provides commitments that such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and

- Describes the site criteria contained in 10 CFR Part 100 and the site characteristics.

If the staff determines that the application satisfies the above criteria, the staff should conclude that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Where an applicant desires approval of design regarding a specific topic, the NRC staff should review the application to determine whether it has provided sufficient information about the topic at a level of detail that is expected at the operating license (OL) stage.

<u>Specific Topic Guidance</u>

<u>SAR Chapters 1-8</u>

Application Guidance

As endorsed in DG-1404 with clarifications, and additions, NEI 21-07, Revision 1, “Technology Inclusive Guidance for Non-Light Water Reactors Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology,” (ADAMS Accession No. ML21250A378), provides an acceptable method for developing portions of a construction permit application within the scope of the LMP in accordance with 10 CFR Part 50 requirements. However, for advanced reactor applicants pursuing a CP application under 10 CFR Part 50 and using an alternative risk-informed performance-based approach, additional information not related to the LMP-based affirmative safety analysis should be provided. Specifically, the additional information is related to the minimum information necessary in a CP application for the staff to issue a CP under 10 CFR 50.35(a) when the applicant has not supplied all of the technical information required to complete the application and support the issuance of a CP which approves all proposed design features (i.e., obtains finality for the design). The staff notes that additional guidance for preparing CP applications can be found in Draft Guide 1404, “Guidance for a Technology-Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors.” As previously stated, SAR chapters 1-8 largely focus on describing the fundamental safety functions of the design and the safety analysis of the facility as a whole for each applicant consistent with the LMP approach. Applicants for a CP are required to include proposed principal design criteria (PDC) specific to their facility designs. Additional discussion regarding proposed PDCs and the limited scope of proposed PDCs developed using the LMP process is provided in main portion of this ISG.

Site Evaluation Guidance

The TICAP guidance (i.e., NEI 21-07, and DG 1404) for SAR Chapter 2 provides guidance for the methodologies and analyses portion of the SAR, but it is limited in the guidance that it provides regarding site evaluations. Although some site criteria are evaluated as part of the LMP process on which the TICAP guidance is based, the LMP process does not provide guidance to adequately address the complete set of site evaluations required by the siting requirements at the CP stage and to support a regulatory decision. The guidance for the content and review for site evaluations, including acceptance criteria and any exceptions and clarifications, is described in DANU-ISG-2022-02, “Site Information,” (ADAMS Accession No. ML22048B541)

Chapter 9 - Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste

For construction permit applicant and staff review guidance refer to DANU-ISG-2022-03, “Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste,” (ADAMS Accession No ML22048B543).

Chapter 10 - Control of Occupational Dose

For construction permit applicant and staff review guidance refer to DANU-ISG-2022-04, “Control of Occupational Dose,” (ADAMS Accession No. ML22048B544).

Chapter 11 - Organization and Human-Systems Considerations

For construction permit applicant and staff review guidance refer to DANU-ISG-2022-05, “Organization and Human-Systems Considerations,” (ADAMS Accession No. ML22048B542).

Chapter 12 - Post-construction Inspection, Testing, and Analysis Program

For construction permit applicant and staff review guidance refer to DANU-ISG-2022-06, "Post Construction Inspection, Testing, and Analysis Program," (ADAMS Accession No. ML22048B545).

Quality Assurance

Application Guidance

An applicant should refer to the guidance in RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, October 2017 (ADAMS Accession No. ML17207A293), which provide an approach acceptable to the staff to establishing and implementing a QA program for the design and construction of nuclear power plants. RG 1.28 endorses, with certain exceptions and clarifications, Part I and Part II of the NQA-1b-2011 Addenda to American Society of Mechanical Engineers (ASME) NQA-1-2008, NQA-1-2012, and NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," for the implementation of a QA program during the design and construction phases of nuclear power plants. Part I and Part II of the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50.

Staff Review Guidance

The staff should review the applicant's quality assurance program description (QAPD) applied to activities for design, fabrication, construction, and testing of the safety-related and safety-significant SSCs of a facility or facilities that may be constructed on the site. The staff will normally plan to inspect the implementation of the QAPD prior to the start of included activities.

The staff's review of the QAPD should ensure that the applicant (and its principal contractors, including but not limited to the reactor vendor, Architect Engineer, constructor, and construction manager) has established a QA program for the design and construction phases in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The QA program should also address the collection of site information. The application must describe how the applicant's QA program meets each criterion of Appendix B, including oversight of the applicant's principal contractors. An applicant may propose alternative QA criteria, provided it justifies exemptions from the associated Appendix B criteria. The staff should expect to review applicant submitted exemption requests where alternate requirements are being proposed to the Appendix B regulations.

If the applicant states that it followed the guidance of NQA-1 and NQA-1b endorsed in RG 1.23, the staff should verify that the applicant did indeed follow that guidance. If the applicant departed from that guidance, the staff should evaluate whether the applicant's proposed QA measures satisfy the applicable Part 50, Appendix B requirements.

NRC SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," (ADAMS Accession No. ML031490421), documents the staff's effort to review international quality assurance standards against the existing 10 CFR Part 50 Appendix B framework and assess approaches for adopting international quality standards for safety-related components in nuclear power plants in the existing regulatory framework. The staff should refer to this document when reviewing an application that uses international QA standards to meet 10 CFR Part 50 Appendix B requirements.

Security

Application and Staff Review Guidance

The applicant should submit the following information and the staff should review this information:

- Information demonstrating that site characteristics are such that adequate security plans and measures can be developed consistent with the guidance in Section 2.1 “Site Characteristics and Site Parameters (Overview),” of DANU-ISG-2022-02, “Site Information,” (note that no Physical Security Plan, Security Training and Qualifications Plan, or Safeguards Contingency Plan information is required at the CP stage).

- Information Security Plan – As discussed in Appendix A of this document, the application should include a plan for the protection of safeguards information (SGI). This plan should be reviewed and approved by NRC (e.g., topical report) during the preapplication period to enable the NRC staff to provide the applicant with SGI documents, as necessary, for the applicant to consider safeguards and security in the design of the facility, development of the physical security program to meet the requirements of 10 CFR Part 73, “Physical Protection of Plants and Materials,” and address safety concerns associated with 10 CFR 50.150, “Aircraft impact assessment,” in its application. Note that additional discussion regarding aircraft impact assessment at the CP stage can be found below.

Emergency Planning

Application Guidance

The applicant is required to provide the information necessary to meet the requirements found in 10 CFR Part 50, Appendix E, Section II, “The Preliminary Safety Analysis Report,” pursuant to 10 CFR 50.34(a)(10). A complete emergency plan is not required for a construction permit. Nonetheless, the preliminary safety analysis report must include information sufficient to ensure the compatibility of proposed emergency plans for both onsite areas and the emergency planning zones (EPZs) with facility design features, site layout, and site location with respect to such considerations as access routes, surrounding population distributions, land use, and local jurisdictional boundaries for the EPZs, as well as the means by which the standards of 10 CFR 50.47(b) will be met.

For CP applicants that may consider providing a complete emergency plan, refer to the “Emergency Preparedness Plan” in the base document for guidance.

Staff Review Guidance

The main body of this document provides staff review guidance in the event the CP application includes a complete emergency plan.

Aircraft Impact

Application Guidance

Construction permit applicants for new nuclear power reactors are required to address the impact of a large commercial aircraft as part of the design. Guidance regarding this assessment can be found in the main body of this document. The regulation found at 10 CFR 50.150 requires applicants to perform the aircraft impact assessment at both the CP and OL licensing stages and include the required information in both applications based on the level of design information available at the time of each application (i.e., complete information at the OL stage).

Staff Review Guidance

The NRC staff should recognize that the information in the CP application may be based on preliminary design information. Staff review guidance regarding this assessment can be found in the main body of this document.

Fitness for Duty

Construction permit applicants for new nuclear power reactors are required to address the fitness for duty (FFD) requirements found in 10 CFR Part 26, "Fitness for Duty Programs." Applicant and staff review guidance regarding this assessment can be found in the main body of this document.

Research and Development

Staff Review Guidance

The staff should review any identified research and development (R&D) program plans that are necessary to resolve any safety questions associated with safety features or components. This review should consider the applicant's plan for research activities including testing of new safety or security features that differ from existing designs for operating reactors, or that use simplified, inherent, or passive means to accomplish their safety or security functions. The staff should verify that the testing ensures that these new features will perform as predicted, provide for the collection of sufficient data to validate computer codes, and show that the effects of system interactions are acceptable.

The staff should ensure that the applicant's commitments to develop sufficient information (through testing or R&D) to support the reliability, availability, and performance of safety-related and safety-significant SSCs and human actions modelled in the final PRA (e.g., commitments for items such as fuel testing and analytical code verification and validation) are completed on a schedule to support the staff's review of the final design.

The staff should ensure that the applicant has provided a summary description of preoperational and startup testing that is planned for each unique or first-of-a-kind principal design feature that may be included in the facility design. The staff may accept information, as applicable, that is sufficient to credit previously performed testing for identical unique or first-of-a-kind design features at other NRC-licensed production facilities.

The staff should determine whether the R&D plans will permit the staff to make the findings required by 10 CFR 50.43(e) (for applications which differ significantly from light-water reactor designs that were licensed before 1997 or use simplified, inherent, passive, or other innovative means to accomplish their safety functions).

Fuel Qualification

Application Guidance

The reactor core and its fuel are generally identified as safety-related due to the direct involvement of the core and fuel in performing fundamental safety functions. The information requirements associated with safety-related SSCs are discussed in Chapter 6, “Safety-Related SSC Criteria and Capabilities,” of the PSAR. However, there are regulatory requirements, such as fuel design limits, that are attributed to or identified with fuel performance and fuel qualification. One of the characteristics of fuel qualification is the need for irradiation data that corresponds to the transient and normal operating conditions expected over the life of the plant. Accordingly, it is anticipated that advanced reactor designs will use existing data (e.g., Advanced Gas Reactor (AGR) program data, legacy metal fuel data) to support regulatory licensing to some degree.

To ensure sufficient staff understanding of the design limits and source term, the application should address uncertainty associated with any limitations on data available at the CP stage. Appendix A of this document recommends that these issues be addressed during the preapplication phase and documented in a topical report that could be reference in the CP application. If the topical report approach is not taken, the following guidance is provided that is based on the discussion found in the Appendix A sections of this document titled, “Safety and Accident Analysis Methodologies and Associated Validation” and “Mechanistic or Accident Source Term Development”:

> Safety and Accident Analysis Methodologies and Associated Validation
>
> Construction permit applicants should develop and execute plans to perform safety and accident analyses that include testing of safety features to support validation and verification of associated engineering computer programs. The approval of these analysis plans needs to include development of associated methodologies and applications of those methods, which include but are not limited to event-specific analysis methodologies, scaling methodology, setpoint methodology, reactor coolant analysis methodology, core design methodology, and reactivity control methods. The analysis plans need to include a test plan and test program to ensure appropriate verification and validation of the engineering computer programs, including consideration of appropriate quality assurance requirements. The test program should satisfy 10 CFR 50.43(e), which requires applicants to demonstrate that sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions.

Mechanistic or Accident Source Term Development

Construction permit applicants should submit their source term methodology to the NRC staff. The source term methodology needs to include radiological source terms for effluents, radwaste system design, shielding design, and equipment qualification and should include validation and verification of associated engineering computer programs.

Staff Review Guidance

Staff review of fuel qualification at the CP stage should focus on (1) understanding the role of the fuel in the safety analysis, and (2) determining the adequacy of the plan to provide the basis for fuel performance relied upon in the safety analysis. Sufficient information should be available to support findings that:

- The role of the fuel in the safety analysis is adequately described. This can be addressed if the application specifies fuel performance during (1) normal operation, including the effects of anticipated operational occurrences, and (2) off-normal conditions, including DBEs, DBAs and BDBEs. In support of these findings, the staff should seek to understand the design limits for the fuel and the source terms associated with event sequences, including anticipated operational occurrences (AOOs), design basis events (DBEs), beyond-design basis events (BDBEs).

- The fuel qualification plan is adequate. Staff evaluation of the fuel qualification plan should consider the proposed analysis methodologies (e.g., fuel performance codes), the use of existing data, and any ongoing testing or plans to utilize lead test specimens. Where legacy data is used, a justification for the applicability of the data to the current application should be provided (e.g., data was collected for a fuel fabricated consistent with the proposed fuel design and irradiated in an applicable environment).

- Two documents provide additional background on non-LWR fuel qualification: (1) NRC guidance in NUREG-2246, “Fuel Qualification for Advanced Reactors,” issued March 2022 (ADAMS Accession No. ML22063A131), and (2) an example of a generic fuel qualification topical report and associated safety evaluation applicable to multiple non-LWR designs “Uranium Oxycarbide (UCO) Tristructural Isotropic (TRISO)-Coated Particle Fuel Performance," issued December 2020 (ADAMS Accession No. ML20336A052).

Regulatory Exemptions

Staff Review Guidance

The staff should review any requested exemptions from NRC requirements. The applicant should refer to Appendix B of this document for guidance regarding the applicability of NRC regulations to its facility.

Environmental Report

Application Guidance

The ER should address the environmental issues described in RG 4.2, “Preparation of Environmental Reports for Nuclear Power Stations,” Revision 3, September 2018 (ADAMS Accession No. ML18071A400), which provides guidance to applicants for the format and content of ERs that are submitted as part of an application for a permit, license, or other authorization to site, construct, and/or operate a new nuclear power plant. The ER should provide a justification for any issue that the applicant believes does not need to be analyzed. See main body of this document for further information on this topic.

Staff Review Guidance

The staff should review an applicant’s environmental report (ER) as part of the CP application in accordance with 10 CFR 51.50(a). Guidance on the review of environmental issues is given in NUREG-1555, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants.” Additional information related to this topic can be found in the main body of this document and in Appendix A of this document, which encourages preapplication discussions in this area. See main body of this document for further information on this topic.

APPENDIX D - Draft Advanced Reactor Content of Application Project Guidance Documents Under Development as of May 2023

The purpose of this appendix is to provide a list of draft guidance documents that are under consideration for future updates to this ARCAP roadmap interim staff guidance (ISG) and other ARCAP ISGs and the technology inclusive content of application project (TICAP) draft regulatory guide (DG). These draft documents are under development and have not received a complete staff review; therefore, they do not represent official NRC staff positions. If an applicant relies on and one of these draft documents, the applicant will be at risk that a final NRC position will conflict with the position provided in the draft document. The first column of the table below provides a listing of the affected ARCAP ISGs and TICAP DG that have the potential to be updated to reflect the final versions of the draft documents listed in the third column. Because this ARCAP roadmap ISG contains a listing of all relevant guidance documents, some draft documents appear twice: once in this appendix to the ARCAP roadmap ISG and, if applicable, a second time in the specific ISG or TICAP DG that is also under consideration for an update.

ARCAP/TICAP Document	Item #	Draft Document Being Considered for Possible Update	Application Content Area	Comments
Draft Interim Staff Guidance DANU-ISG-2022-01 “Advanced Reactor Content of Application Project, ‘Review of Risk-Informed, Technology Inclusive Advanced Reactor Applications – Roadmap.’”	1	An appendix to DG-1404 is being considered for development to provide additional guidance for the scope, level of detail, elements, and plant representation for a probabilistic risk assessment (PRA) supporting a Licensing Modernization Project (LMP)-based	TICAP/PRA	This guidance, if issued, would supplement the guidance in RG 1.247 for trial use. During an April 18, 2023, public meeting on the topic (see: https://www.nrc.gov/pmns/mtg?do=details&Code=20230362) the NRC staff outlined an approach for the development of guidance in this area.

ARCAP/TICAP Document	Item #	Draft Document Being Considered for Possible Update	Application Content Area	Comments
		construction permit application		
	2	Draft interim staff guidance (ISG) is being considered for development associated with the relationship between the type of licensing applications and the Capability Categories of the supporting requirements in ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plant," (i.e., NLWR PRA standard).	TICAP/PRA	This guidance, if issued, would supplement the guidance found in RG 1.247. The guidance is being considered because some supporting requirements in the NLWR PRA standard are not applicable to certain plant applications or stages, while other supporting requirements need some clarification to understand how they can be achieved.
	3	Preliminary Draft Regulatory Guide DG-1413, "Technology-Inclusive Identification of	TICAP/PRA	This guidance, if issued, would supplement the guidance found in RG 1.247. The guidance provides the staff's technology-inclusive guidance for identifying initiating events, delineating event sequences and licensing events that can be used to inform the design basis, licensing basis, and content of applications for commercial nuclear plants.

ARCAP/TICAP Document	Item #	Draft Document Being Considered for Possible Update	Application Content Area	Comments
		Licensing Events for Commercial Nuclear Plants" (ADAMS Accession No. ML22146A045)		Several of the beginning steps proposed in this guidance are applicable to the development of a probabilistic risk assessment (PRA)
	4	A Draft ISG is being considered for development that would provide guidance for treatment of consequence uncertainty in a PRA.	TICAP/PRA	The guidance, if issued, would supplement the guidance found in RG 1.247. Key to the approach in RG 1.247 is the development of frequency consequence criteria. While guidance for the treatment of uncertainty for the frequency of an event is considered sufficient, the staff is considering the development of additional guidance for the treatment of uncertainty in consequence evaluations.
	5	DANU-ISG-2023-01, "Material Compatibility"	TICAP	The guidance DANU-ISG-2023-01, "Material Compatibility" will identify areas of review that could be necessary in a submittal seeking to use materials allowed under American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (ASME Code), Section III, "Rule for the Construction of Nuclear Facility Components," Division 5, "High Temperature Reactors" (Section III-5) (ASME, 2017). Section III-5 specifies the mechanical properties and allowable stresses to be used for design of components in high temperature reactors (HTRs). However, as stated in Section III-5, HBB 1110(g), the rules do not provide methods to evaluate deterioration that may occur in service as a result of corrosion, mass transfer phenomena, radiation effects, or other material instabilities. This ISG will identify information that the staff should expect to see in advanced reactor applications to satisfy applicable design requirements

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				including qualification and monitoring programs for safety-significant structures, systems, and components (SSCs).
	6	Potential update to Regulatory Guide 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,” Revision 0.	Site Information	The staff is considering updating this guidance document to endorse the following standard with appropriate additions, and clarifications: • ANSI/ANS-2.27-2020, “Criteria for Investigations of Nuclear Facility Sites for Seismic Hazard Assessments • ANSI/ANS-2.29-2020, “Probabilistic Seismic Hazard Analysis” • ASCE/SEI 43-19, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities” Applicants that wish to use these standards prior to the issuance of the Revision to RG 1.208, should discuss their plans with the NRC staff during the preapplication phase. The NRC staff further notes that the guidance in ASCE/SEI 43-19 uses a graded approach and that SSCs designed to seismic design criterion 5 would generally meet the requirement in 10 CFR Part 50 Appendix S. For SSCs designed to other seismic design criteria the applicant needs to demonstrate these SSCs have sufficient margin such that 10 CFR Part 50 Appendix S requirements are met. If an applicant is using multiple design spectra that do not meet 10 CFR Part 50 Appendix S, the applicant should engage the staff during preapplication phase to discuss their plans.
	7	DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering	Safety Analysis Report (SAR) Chapter 11 Human Factors Engineering	Update to ARCAP Ch. 11 under consideration. Draft of DRO-ISG-2023-03 was issued September 29, 2022 (ADAMS Accession No. ML22272A051)

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		Review Plans, Draft Interim Staff Guidance”		
	8	DG-1350, proposed RG 1.242, “Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities,” (ADAMS Accession No. ML18082A044)	Emergency Preparedness Plan	Draft guidance included as part of SECY-22-0001, “Rulemaking: Final Rule Emergency Preparedness for Small Modular Reactors and Other New Technologies (RIN 3150-AJ68; NRC-2015-0225)”
	9	DG-5071 – “Target Set Identification and Development for Nuclear Power Reactors” (Note that this is a revision to RG 5.81, “Target Set Identification and Development for Nuclear Power	Physical Security	Updates to Physical Security Guidance under consideration. This DG was provided to the Commission for consideration as part of the physical security rulemaking. The Commission approved a proposed rule in this area (see: SRM-SECY-22-0072, “Proposed Rule: Alternative Physical Security Requirements for Advanced Reactors (RIN 3150-AK19).”

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		Reactors," December 2019 (Official Use Only – Security Related Information)		
	10	DG-5072 – "Guidance for Alternative Physical Security Requirements for Small Modular Reactors and Non-Light-Water Reactors" (ADAMS Accession No. ML20041E037)	Physical Security	See DG-5071 (item #1) comment
	11	U.S. Nuclear Regulatory Commission, Advanced Nuclear Reactor Generic Environmental Impact Statement (GEIS)	Environmental Report and Site Redress Plan	Information regarding the status of this effort can be found at: https://www.nrc.gov/reactors/new-reactors/advanced/details.html#advRxGEIS
DG-1404, "Guidance for a Technology-Inclusive Content of Application Methodology to Inform the	12	TICAP	SAR Chapters 1-8	See items 1 through 5 above

ARCAP/TICAP Document	Item #	Draft Document Being Considered for Possible Update	Application Content Area	Comments
Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Advanced Reactors." (TICAP)				
Draft Interim Staff Guidance DANU-ISG-2022-02, "Advanced Reactor Content of Application Project Chapter 2, 'Site Information.'"	13	Update to RG 1.208	Site Information	See item 6 above
Draft Interim Staff Guidance DANU-ISG-2022-05, "Advanced Reactor Content of Application Project Chapter 11, 'Organization and Human-System Considerations.'"	14	DRO-ISG-2023-03, "Development of Scalable Human Factors Engineering Review Plans, Draft Interim Staff Guidance"	SAR Chapter 11 - Human Factors Engineering	See Item 7 above